2019

Developing standards for labelling dispensed medicines

Report on user testing findings

CONFIDENTIAL

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Research team

The research team involved in this study comprised the following members:

- Professor Parisa Aslani (PA)
- Ms Sophie Carter (SC)
- Ms Shrada Chitlangia (SCh)
- Ms Jackie Crofton (JC)
- Dr Alice Gilbert (AG)
- Mr Daniel Lalor (DL)
- Mr Brian Parkinson (BP)
- Ms Wing Poon (WP)
- Professor David K Raynor (DKR)
- Ms Diana Shipp (DS)
- Mr Andrew Sobey (AS)
- Dr Vivien Tong (VT)
- Ms Joanne Young (JY)

PA, DKR, VT and BP developed, reviewed and refined the labels. PA, VT and DKR developed the user testing questionnaire. JC, AG, DL, AS, DS and JY reviewed and commented on the labels developed. SC and VT recruited participants and conducted the user testing and qualitative interviews. VT, SC, SCh, WP and PA conducted the data analysis.

The research team have extensive experience in written medicine information development, health communication, information design, and written medicine information evaluation, and/or a background in pharmacy practice (hospital and/or community pharmacy).

Funding

Funding for this study was received from the Australian Commission on Safety and Quality in Health Care.

Acknowledgements

The research team acknowledges all study participants for their time and contributions towards this research study.

Glossary and key abbreviations

Core UTQ items	Core user testing questionnaire items reflecting key information items found on the labels. All core UTQ items have been listed in Table 4, and include the "standard" information content.
FTA	Fingertip amount
PIL	Patient information leaflet
Prn medicine	"As required" medicine
Probe question	A follow-up question asked once the key information has been found, in response to a question in the core UTQ, in order to explore the extent of the person's understanding and/or ability to apply the information.
"Standard" information content	The standard information found on a dispensed prescription medicine label: the patient name, prescriber name, expiry date, date of dispensing, pharmacy name and address, and reference number. This information was consistent on all labels evaluated in this study.
UMS	Universal Medication Schedule
UTQ	User testing questionnaire
User testing industry standard	*"90% of the test participants are able to find the information requested within the PIL, of which 90% can show that they understand it."*[1(p.6)]

Executive summary

Introduction

Dispensed prescription medicine labels are critical, tailored medicine information sources that support safe and appropriate medicines use by consumers. Legislative requirements govern label content, thus enabling consistent information to be provided. However, there are no Australian legislative requirements or national standards which govern or guide the way information should be included on the label or the overall label format. Labels represent the mainstay of prescription medicine information. However, there is limited data determining their usability and role as a communication tool for medication taking in populations with low health literacy. A large proportion of the Australian population has low health literacy. Therefore, it is possible that a large proportion of consumers are likely to have difficulty with understanding and appropriately acting on the information, in particular the instructions for use, included on dispensed prescription medicine labels. This may compromise medication safety and quality use of medicines. A national round table in 2013 made recommendations for dispensed labelling. However, there remains a lack of national standardised guidelines in Australia to support the development of user-friendly dispensed prescription medicine labels where specifically the instructions for use can be easily understood by consumers with low health literacy.

Aims

This study therefore aimed to:

1. Develop and user test dispensed prescription medicine labels with Australian consumers, focusing primarily on the instructions for use.
2. Explore consumer perspectives on the proposed dispensed prescription medicine label content and design aspects that require improvement.

Methods

This study consisted of five stages:

1. Development of labels for Round 1 user testing evaluation
2. Round 1 user testing (conducted with 40 participants)
3. Iterative revisions of Round 1 labels, leading to the development of Round 2 labels
4. Round 2 user testing (conducted with 20 participants)
5. Final label development for quantitative evaluation and derivation of evidence-based recommendations to help inform a national standard for dispensed prescription medicine labels

User testing

'User testing' is a diagnostic process using individual interviews with small numbers of lay people.[2] It determines whether the key information in the document is easy to find and to understand. After testing, good practice in information writing and design is applied to address shortcomings identified, and testing is repeated in an iterative fashion. It is widely used in the European Union, where legislation has led to manufacturers undertaking user testing on all patient information leaflets. Without such testing, a license will not be granted. As a form of diagnostic testing, only small numbers of people (generally cohorts of 10) are needed to diagnose where there are problems.

Development of labels for Round 1 user testing evaluation

A total of 12 labels for 4 fictitious medicines of varying dosage forms (Table A) were developed using existing medicine information writing and design guidelines and through iterative discussions within the research team. Label characteristics that were taken forward for evaluation included design, formatting, content, and dosage form-specific information variations. Each developed label displayed different combinations of the varied label characteristics. Both small (80 mm x 40 mm) and large (102 mm x 52 mm) label sizes were evaluated.

Table A. Fictitious medicines and active ingredients

Brand name	Active ingredient	Strength	Dosage form	Comments
Lubidrops	Hypromethylmellose	1%	Eye drops	
Mixicillin	Pentoampicillin	500mg/5mL	Suspension	For child
Vipparoll	Myclofenac	75mg 75mg/5mL	Capsules / Tablets Suspension	
Tapisoy	Ocylohydrosteroid	0.05%	Cream	

Round 1 user testing

User testing was used to evaluate the 12 study labels to determine people's ability to find and understand key medicine information. A study-specific user testing questionnaire (UTQ) was developed together with model answers, and used to evaluate key outcome measures related to label formatting, design, content and dosage form-specific information. The primary study outcome measures were a) the ability to find the relevant information, and b) the ability to understand the information that was found.

Forty participants took part in Round 1. Participants were recruited according to study inclusion criteria. In line with user testing protocol, demographically similar cohorts of 10 participating consumers were allocated to user test three labels. Each participant evaluated three unique labels for different dosage forms in the following order:

1. A tablet or capsule label;
2. A suspension label; and
3. An eye drops or cream label.

The three primary interview components of the user testing process were:

(i) Administration of the core UTQ items for the first label (tablet or capsule);
(ii) Administration of core UTQ items pertaining to directions for use for the remaining labels (i.e. suspension; eye drops or cream); and
(iii) A semi-structured interview component.

Additional probe questions relating to the understanding and application of information about pain and application of a cream were also asked for the relevant labels.

Questions in the core UTQ (or core UTQ items) regarding the "standard" information content were asked in relation to the first label user tested by each participant, that is, the tablet or capsule label. The "standard" information content was defined as information other than the directions for use and medicine name, and including the patient name, prescriber name, expiry date, date of dispensing, pharmacy name and address, and reference number, that were consistent on all labels. Two key points of information were used as proxies to evaluate the "standard" information content. These were questions on patient name and expiry date. For the remaining two labels, that is the suspension label and the eye drops or cream label, UTQ items were centred on the directions for use only. Therefore, directions for use were evaluated in all three labels by each participant.

Interviews were conducted face-to-face at The University of Sydney School of Pharmacy by a researcher trained in user testing (VT or SC; between December 2017 and January 2018).

Revisions after Round 1 and conducting Round 2 user testing

Round 1 user testing of the 12 labels led to the development of the labels user tested in Round 2. A total of 6 labels were developed for evaluation, together with a new label proposed by the research team members based at Canberra Hospital. This new label was based on the Universal Medication Schedule (UMS) developed and evaluated by Wolf et al.[3, 4]

Round 2 recruitment and interviews took place in April 2018 with 20 participants in total. Participants each user tested four labels (three unique labels per cohort of 10 participants, and one common label tested by all 20 participants).

Study inclusion / exclusion criteria, recruitment strategy, and overall structure of the face-to-face interview sessions between Rounds 1 and 2 remained unchanged. However, the UTQ items from Round 1 were re-ordered, where necessary, and administered depending on the labels evaluated by the participants in Round 2.

Data analysis

Core UTQ

All interviews except one were audio recorded with permission from the participants. All audio recordings were reviewed by at least two members of the research team. Responses to each UTQ item were transcribed verbatim and coded by two different research team members against the model answer for the primary outcome measures: ability to find the relevant information and ability to understand the information that was found. Where necessary, responses were coded by a third researcher with extensive experience in user testing to resolve any coding discrepancies or queries.

Label performance against industry standards

In order to provide an overall measure of the performance of each label, user testing industry standards criteria were adapted and applied to the quantitative results. In order to satisfactorily meet the standard, there was a requirement that:

- a minimum of 9/10 participants were able to find the information, **and**
- **of these**, 9 participants would have had to demonstrate complete understanding for each key point of information.

Analysis of participant responses to the probe questions

Probe questions relating to two scenarios, one involving pain that started at 9 am, and another involving the amount of cream to be applied, were analysed separately to the core UTQ items. Inductive analysis of the responses informed the development and refinement of a coding framework. Consideration was given to the intended meaning of the directions for use on the labels and how the directions were then applied.

Semi-structured interview analysis

All semi-structured interview components of each face-to-face session were transcribed verbatim and checked for accuracy against the audio recording. The transcripts were then thematically analysed with the help of matrix displays as appropriate. Themes and subthemes were inductively derived and grouped.

Results

Participant overview

Forty participants took part in Round 1 of the user testing; and 20 in Round 2. Overall, there were approximately equal numbers of males and females, with the majority having completed the Higher School Certificate or a college qualification. The vast majority of participants self-reported to be extremely or quite confident in completing medical forms by themselves. Unless specified, the data presented here is grouped data from both rounds of user testing (Round 1 plus Round 2 data).

Overview of user testing findings

In Round 1, across all 12 label formats, medicine strength and dosage were generally well found and understood; at least 8/10 participants found **and** understood the relevant information on each label. This was similar in Round 2, except for the medicine strength on one label (eye drops). Participants' ability to correctly identify the active ingredient varied considerably between labels across both rounds of testing. This was influenced by the positioning and formatting of the active ingredient and brand name.

Comparison of label performance against industry standard

Excluding the responses for the core UTQ items relating to the active ingredient and dosing schedule scenario, 14 of the 19 labels evaluated met the industry standard on performance: 8/12 of the Round 1 labels, and 6/7 of the Round 2 labels. Overall label performance improved between Round 1 and Round 2 (Table B).

Only 2 labels from Round 2 (Labels 15 and 16) enabled all participants evaluating each respective label to find and understand the active ingredient. This is attributed to the clear sign-posting of the active ingredient and brand name.

Active ingredient identification and impact of formatting

Formatting was varied across the labels when communicating the active ingredient and brand name. This subsequently influenced participants' ability to identify the active ingredient and the brand name. Broadly, formatting combinations that appeared to impact participant identification and differentiation between active ingredient and brand name included:

Active ingredient presented in bold or upper case bolded font – Bolding of the active ingredient (and active ingredient printed in upper case bolded font) appeared to contribute to poorer participant ability to correctly identify the active ingredient (Labels 3, 4, 6, 7, 8 compared to Label 1).

Formatting in contrast to current practice – The worst performing label was Label 14B, where only 1/10 participants could correctly determine the active ingredient. This was due to formatting the active ingredient and brand name in direct opposite of current practice; that is, active ingredient presented in bold first, followed by the brand name in brackets.

Sign-posting of active ingredient and brand name – The best performing labels were Labels 15 and 16. All participants could correctly determine the active ingredient. This was due to the active ingredient and brand name being clearly sign-posted on the label.

Active ingredient included in brackets – The inclusion of the active ingredient in brackets appeared to improve participants' ability to identify the active ingredient for the cream when comparing the performance of Round 1 and Round 2 cream labels.

Active ingredient and brand names – Overall, the eye drops labels supported the most consistent correct identification of active ingredient, despite having the same formatting applied to both active ingredient and brand name. The lengthy and technical active ingredient name likely contributed to this.

Table B. Summary data of label performance in relation to industry user testing standards

Dosage form	Round	Label	Met industry requirements for all UTQ items[a]	UTQ item(s) responsible for not meeting minimum requirements
Tablets / Capsules	Round 1	1	✓	
		3	✓	
		4	✓	
		8	×	Medicine strength Maximum dose (*as required or prn medicine*)
	Round 2	13	✓	
		14A	✓	
		14B	✓	
Suspension	Round 1	6	✓	
		7	✓	
		9	✓	
		10	✓	
	Round 2	15	✓[b]	
		16	✓[b]	
Cream	Round 1	2	✓	
		5	×	Medicine strength
	Round 2	17	✓	
Eye drops	Round 1	11	×	Medicine strength
		12	×	Medicine strength
	Round 2	18	×	Medicine strength

[a] UTQ data for active ingredient identification and data related to UTQ item on dosing schedule tabulation excluded.
[b] Labels 15 and 16 explicitly stated which was the active ingredient and which was the brand name (sign-posting). They demonstrated superior performance regarding active ingredient identification over all other labels.

Communication of dosage information and directions for use

Across all label formats, participants demonstrated satisfactory ability to find and understand the directions for use on the labels. Consequently, no marked difference in dosage understanding was seen between the use of words or numbers to convey numerical dosage information on the study labels.

Dosing schedule scenario

Participants were asked to plan a daily medication schedule for four medicines, with one of these medicines being the tablets or capsules corresponding to the study label being evaluated. Overall, in Round 1, 28/40 participants were able to plan an appropriate schedule. For those who nominated inappropriate schedules, 9/12 participants demonstrated scheduling issues for the three medicines X, Y, or Z (listed on the show card that was provided for this question). For the remaining 3/12 participants, issues were seen in relation to the study label, Vipparoll (tablets or capsules), where either the evening dose was missing, or issues were seen relating to observing the 6-hour dosing interval.

In comparison, in Round 2, 8/20 participants planned inappropriate schedules. Of these eight participants, three demonstrated Vipparoll dosing issues where the time between the evening and bedtime doses were specified as less than 6 hours (Label 14A).

Probe question and impact of dosage expression

Participants were asked to explain how they would take the medicine (Labels 1, 2, 4, 8, 14A and 14B) for the rest of the day if their pain started at 9 am. The largest proportion of Round 1 participants who gave an appropriate dosing schedule with appropriate dosing intervals was observed for Label 8 (Table C). An explicit dosing interval of 6 hours was written on Label 8, which may explain the appropriate dosing specified by the participants. Doses were appropriately spaced by 7 and 9 participants if the label stated the frequency of doses per day (Label 1) or a specific dosing interval (Label 8), respectively.

In Round 2, all participants evaluating Label 14B reported appropriate dosing intervals for the medicine, while 3/10 reported an omitted dose for Label 14A. Adhering to the 6-hour dosing interval took precedence over the direction to take 4 doses per day for these participants. A further 2/10 participants did not consistently observe the 6-hour dosing interval.

Table C. Data on appropriate dosing for pain scenario

Label	Dosage expression	Appropriate dosing intervals (number of participants)	Inappropriate dosing interval(s) (number of participants)			
			Shorter dosing interval(s)	Longer dosing interval(s)	Shorter and longer dosing intervals	Dose omitted
1	Frequency of doses per day	7	3	0	0	0
3	Approximate times of day for dosing	3	6	0	1	0
4[a]	Tabulated dosing schedule with explicit times	7/10 correctly cited the dosing times in accordance with the dosing table when asked the UTQ item regarding dosage 3/10 participants were further probed, and correctly nominated dosing times in line with the dosing table				0
8	Explicit dosing interval	9	0	1	0	0
14A	Tabulated dosing schedule with only approximate times of day; explicit interval	5	2	0	0	3
14B	Tabulated dosing schedule with explicit times	10	0	0	0	0

[a] N.B. Label 4 contained the table with specific times at which the doses were to be taken. Therefore, the probe question was only asked if the participant did not specify times at which they would take the medicine as part of their first response.

Application of cream

When asked how much cream they would apply, participants user testing Label 5 (which did not provide an indication of an amount or "dose") reported that the label did not specify an amount of cream to be applied, and the amount of cream to be applied was deemed to be dependent on:

- Size of the rash
- A perceived appropriate amount, for instance to cover the area or a thick layer
- The effect of the cream, which would be monitored once applied, with the observed effect then determining further action; for instance, an adjustment of the amount of cream to be applied

In contrast, when probing participant understanding of "1 fingertip amount", in general, participants either intended to squeeze or dab the cream onto the fingertip and ensure that there was enough to cover the area, or said they would just squeeze a small amount onto their fingertip. The question was also raised about what constituted a fingertip.

Medicine strength

Labels for non-solid dosage forms demonstrated issues with regards to participant understanding of the medicine's strength. Although the quantitative user testing findings for suspension labels did not suggest an issue, one participant who evaluated Label 15 struggled with the suspension strength and dosage; the participant was confused between strength (expressed in 5 mL increments) and dosage (9.5 mL dose). Qualitative feedback from participants also indicated that the medicine strength for the suspension was not clearly communicated when expressed in the format "500mg/5mL". A statement explaining the medicine strength was well received overall, as included on Label 15 in Round 2 ("Each 5 mL of the syrup contains 500 mg pentoampicillin").

The strength of the cream proved problematic for 2/10 participants evaluating Label 5 (Round 1). The amount of active ingredient in the cream was specified by the two participants as 25 g or 50 g, respectively, rather than 0.5%, as per the label. The cream quantity indicated on the label was 50 g, which suggested that the participants were confused between the medicine strength and the total amount of cream. Similarly, in Round 2, one participant was confused between the strength and the quantity of the cream, as they did not find the information and stated 50 g, not 0.5%, as the strength.

A marked difference in understanding the medicine strength for the eye drops labels between Rounds 1 and 2 was noted. In Round 1, two participants did not understand the information about the strength of the eye drops; they did not understand what 1% meant. The most notable finding for the Round 2 eye drops label was that 4/10 participants were unable to find the strength of the eye drops. Participants said the eye drops contained 10 mL of active ingredient, highlighting confusion between the quantity of the eye drops and the strength, which can be linked to a label formatting change that was made in the information position on the label.

"Standard" information content evaluation across the different label formats

In both Round 1 and 2, at least 9/10 participants were able to both find **and** understand the patient name and expiry date of the medicine from each label, indicating that the label formats used (single column or two column format, and variations in "standard" information content positioning within these broader formats) were effective in supporting participants.

Conclusions

A total of 19 labels were developed based on good information writing and design principles and evaluated through 2 rounds of user testing by 60 participants. Overall, the majority of labels evaluated met user testing industry standards criteria (when excluding the active ingredient and dosing schedule UTQ item responses). That is, a minimum of 9/10 participants were able to find the information, and of these, 9 participants demonstrated complete understanding for each key point of information evaluated. Label format and label size did not appear to impact participants' ability to determine the patient name and the expiry date of the medicine ("standard" information content).

Labels failed to meet industry standards criteria due to the information related to active ingredient and medicine strength, which were found by participants as either difficult to find or difficult to understand. Label design formatting did have a notable impact on active ingredient identification. Actively specifying or sign-posting the active ingredient and brand name was the most effective labelling strategy to improve participants' ability to identify the active ingredient on the label.

Use of a tabulated dosing schedule on the label was positively received by participants and may assist people with scheduling their medicines.

Recommendations

The following recommendations are put forward based on the evidence from the two rounds of user testing. It should be noted that the evidence for all recommendations can be found in the full report:

1. Active ingredient and brand name formatting:
    - Sign-posting of active ingredient and brand name on the label, especially if intending to change the current labelling practice and including the active ingredient as the first name
2. Communication of medicine-related information:
    - Clearly stating the specific dosing interval using a narrow range
    - Using numbers to convey numerical dosage quantities, where appropriate
    - Specifying the units immediately after expressing pack size and quantity of medicine, for example 100 capsules not just “100”
    - Expressing medicine strengths using clearer statements
    - Expressing discard-by information as weeks where possible, rather than days
3. Design, formatting, and layout:
    - Using bullet points for information such as explanations
    - Bolding key terms and phrases on label
    - Using a tabular format, where appropriate, on labels to express dosage and frequency of medicine use
    - Separating patient and medicine-specific information from other details included on the label (for example, pharmacy address, date of dispensing)

It is also important to reiterate that optimal usability of the content of any label should be established by user testing prior to the label format(s) and content(s) being implemented in practice.

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1. Introduction

Pharmacy-produced labels for dispensed prescription medicines are an important method for communicating medicines information to consumers and to ensure correct use of their medicine(s). In Australia, all dispensed prescription medicines are legally required to have a label before being provided to a patient in the community. The information content of the label is governed by legislative requirements, for example, the Poisons and Therapeutic Goods Regulation 2008 – Appendix A[5] for New South Wales. A label is required to have information such as the name of the patient, date of dispensing, name and address of the pharmacy (or health care provider) dispensing the medicine, name, strength and dosage form of the medicine as well as the instructions for use. Often the dispensed prescription medicine label is the only medicine information the patient has, especially if they have not received more detailed medicine information leaflets or have forgotten the verbal information provided to them by their pharmacist or doctor.

The dispensed prescription medicine label is tailored information for the consumer, as it states how the consumer should be taking or administering their medicine. However, the information included on a label can be misunderstood. It has been estimated that about 60% of Australians (aged between 15 and 74 years) do not have the basic health literacy skills that are needed to understand health-related information,[6] such as instructions for use typed on dispensed prescription medicine labels. There is a high probability that a large proportion of consumers will have difficulty in understanding the instructions on labels. This may lead to inappropriate use of medicines and consumer harm.

Within the Australian context, the Australian Commission on Safety and Quality in Health Care published a report following a national round table held in 2013.[7] As part of this report, a series of recommendations to form an Australian standard for labelling were put forward, which were *"derived from health literacy studies, work undertaken by the United Kingdom's former National Patient Safety Authority, the United States Pharmacopeia prescription container labelling standards and an American College of Physicians Foundation white paper"*.[7(p.7)] However, there is no nationally implemented guidelines available for the presentation of information on dispensed prescription medicine labels. Therefore, this study aimed to address this gap through the development and evaluation of dispensed prescription medicine labels which can be read and understood by consumers, including those with low health literacy. The findings of this study will inform a national dispensed medicine label standard.

2. Methods

2.1 Study aims

The aims of this study were to:

- Develop and user test dispensed prescription medicine labels with Australian consumers, focusing primarily on the instructions for use.
- Explore consumer perspectives on the proposed dispensed prescription medicine label content and design aspects that require improvement in future.

2.2 Ethics approval

Research ethics approval for the conduct of this study was granted by The University of Sydney Human Research Ethics Committee [2017/620]. All participants who completed a face-to-face interview session as part of this study were reimbursed $40 for their time involved in study participation.

2.3 Overview of research study design

This research study consisted of five stages:

1. Development of labels for Round 1 user testing
2. Round 1 user testing
3. Iterative revisions of Round 1 labels, leading to the development of Round 2 labels
4. Round 2 user testing
5. Final label development for quantitative evaluation and provision of evidence-based recommendations to help inform a national standard for dispensed prescription medicine labels

2.4 User testing

In order to test the prescription label formats, user testing[2, 8] was conducted with consumers to measure the performance of the study dispensed prescription medicine labels.

User testing is an iterative, performance-based method – it determines whether people can find and understand the information they need to take the medicine safely and effectively. It has also been called 'diagnostic testing'– as it diagnoses where there are problems in a document. It was developed in Australia in the 1990s by Professor David Sless at the Communication Research Institute. Because it is a diagnostic process, only small numbers of participants are needed to identify the key problems in a piece of information. It differs from content-based testing, such as readability formulas, which are proxies for whether the document actually works in practice. User testing has four key attributes:

- Individual interviews with people in target group – to test the information with lay people with a range of abilities and backgrounds (including people who do not use written documents in their working life).

- Participant uses the information to answer the questions – to mimic the situation when someone uses the information.
- Mixed methods – the interview has both quantitative and qualitative aspects. Firstly quantitative, to assess whether people can they find and understand key points of information. This is followed by a brief qualitative semi-structured interview where the participant's general views on the information are gathered – things they liked and did not like.
- Iterative process – testing is followed by revision to address the problems identified, using best practice in information writing and design. It is then tested again on a new cohort of participants (to prevent a learning effect).

User testing itself does not improve a document – it is the expertise applied to resolve problems identified, that is the key.

2.5 Development of labels for Round 1 user testing evaluation

As an initial step, a series of 12 labels were developed for four different fictitious active ingredients with various dosage forms (Table 1), using principles of good information writing and design[9, 10] and subsequent iterative discussions among the research team members.

Table 1. Fictitious medicines and active ingredients

Brand name	Active ingredient	Strength	Dosage form	Comments
Lubidrops	Hypromethylmellose	1%	Eye drops	
Mixicillin	Pentoampicillin	500mg/5mL	Suspension	For child
Vipparoll	Myclofenac	75mg 75mg/5mL	Capsules / Tablets Suspension	
Tapisoy	Ocylohydrosteroid	0.05%	Cream	

Label characteristics were agreed upon by the research team members to ensure that a wide spectrum of factors was evaluated. These included:

Label size

- The small labels were 80 mm x 40 mm in size, with the main directions and "standard" information content printed in 8 point and 7 point Arial font, respectively
- The large labels were 102 mm x 52 mm in size, with the main directions and "standard" information content printed in 10 point and 9 point Arial font, respectively

Formatting variations

- Brand and active ingredient names – In upper case, sentence case, lower case, italics (although use of italics was limited as evidence shows that italics impedes readability[9, 10])
- Dose instructions – Bolding versus no bolding; and mixed use of bolding / non-bolding (action, number of dose, frequency of administration)
- Dose instructions – List of when to take / use the medicine (bulleted and non-bulleted) versus continuous sentence

Content variations

- Number of tablets / capsules – Numerical versus words

- Time of dosing – Inclusion of time of dosing versus no timing
- Dosing table – Inclusion of table (adapted from the Universal Medication Schedule (UMS) table[4]) versus no table to illustrate dosing (in addition to instructions)

Dosage form-specific content variations

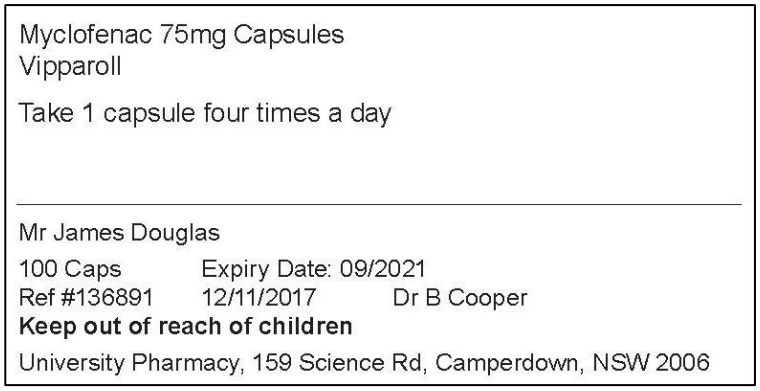
- Cream – Instructions for use
- Oral liquid / suspension – Instructions for use; and instructions for administration to a child
- Eye drops – Instructions for ocular dosing
- Options for "when needed" dosing (where some wording aspects were adapted from the Take-Wait-Stop strategy[11] for Label 9)

Due consideration was also given to the relevant national standards and guidelines on presentation of medicine information when developing the study labels (Appendix 1).

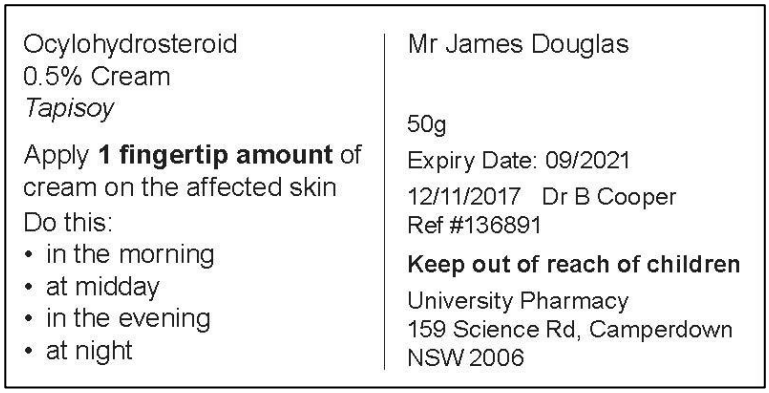
2.5.1 Labels evaluated in Round 1 user testing

The following labels were developed for evaluation as part of Round 1 of user testing. Each label included different combinations of the designated label variables (Table 2).

Label 1
(102 mm x 52 mm)



Label 2
(102 mm x 52 mm)



Label 3
(80 mm x 40 mm)

Myclofenac
75mg Tablets
Vipparoll

Take
2 tablets in the **morning**
2 tablets at **midday**
2 tablets in the **evening**
2 tablets at **night**

Mr James Douglas

100 Tabs
Expiry Date: 09/2021
12/11/2017 Dr B Cooper
Ref #136891
Keep out of reach of children
University Pharmacy
159 Science Rd,
Camperdown NSW 2006

Label 4
(102 mm x 52 mm)

Myclofenac 75mg Capsules
Vipparoll

Take **ONE** capsule **four times a day**

Morning (7 to 9am) 1 capsule	**Midday** (12 to 1pm) 1 capsule	**Evening** (4 to 6pm) 1 capsule	**Bedtime** (9 to 11pm) 1 capsule

Mr James Douglas 100 Caps Exp: 09/2021
Ref #136891 12/11/2017 Dr B Cooper
Keep out of reach of children
University Pharmacy, 159 Science Rd, Camperdown, NSW 2006

Label 5
(80 mm x 40 mm)

Ocylohydrosteroid
0.5% Cream
Tapisoy

Apply the cream on the affected skin in the morning and at night

Mr James Douglas

50g
Expiry Date: 09/2021
12/11/2017 Dr B Cooper
Ref #136891
Keep out of reach of children
University Pharmacy
159 Science Rd,
Camperdown NSW 2006

Label 6
(102 mm x 52 mm)

PENTOAMPICILLIN 500mg/5mL Suspension
Mixicillin

Measure 9.5mL of the liquid, and give to the **child three times a day**, with food

Master James Douglas
100mL Expiry Date: 09/2021
12/11/2017 Dr B Cooper
Ref #136891

Keep out of reach of children
University Pharmacy
159 Science Rd, Camperdown
NSW 2006

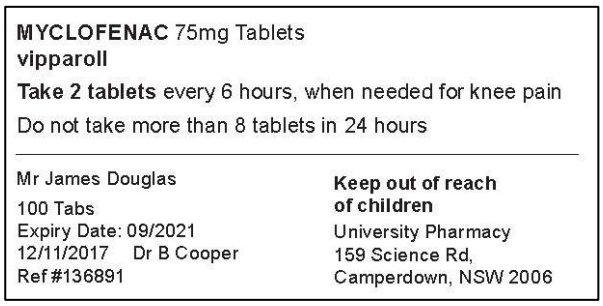
Label 7
(80 mm x 40 mm)

PENTOAMPICILLIN 500mg/5mL Suspension
mixicillin

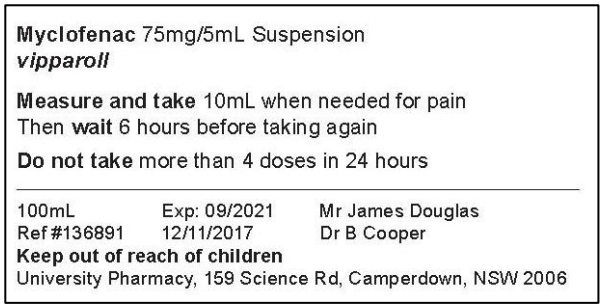
Measure and give liquid to the child, with food
- **9.5mL** in the morning
- **9.5mL** in the afternoon
- **9.5mL** at night

Master James Douglas 100mL Exp: 09/2021
Ref #136891 12/11/2017 Dr B Cooper
Keep out of reach of children
University Pharmacy, 159 Science Rd, Camperdown, NSW 2006

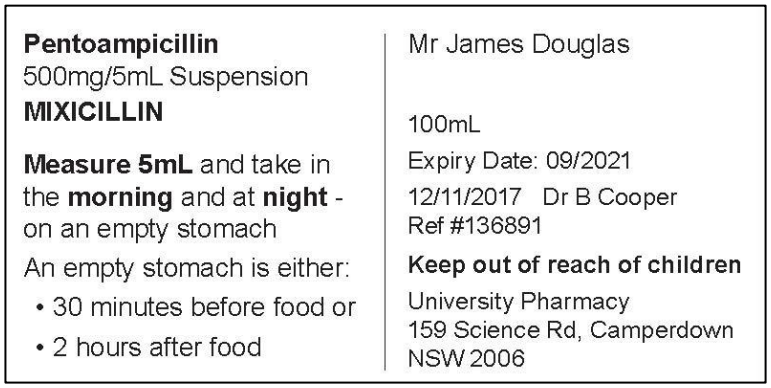
Label 8
(80 mm x 40 mm)



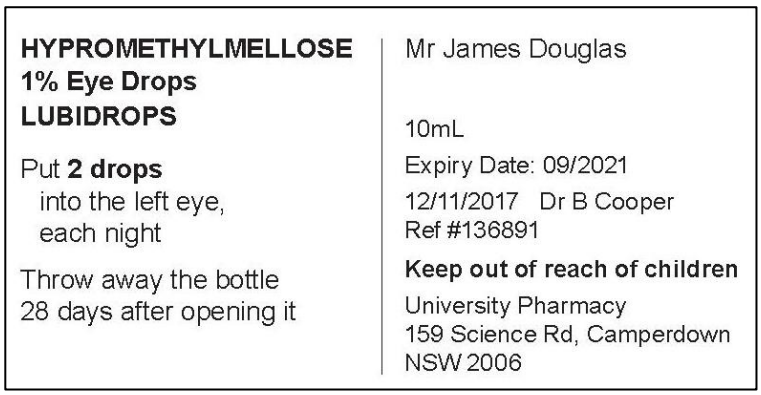
Label 9
(80 mm x 40 mm)



Label 10
(102 mm x 52 mm)



Label 11
(102 mm x 52 mm)



Label 12
(80 mm x 40 mm)

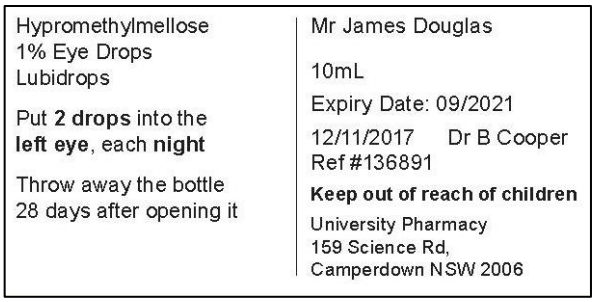


Table 2. Variations in labels evaluated in Round 1 of user testing

Label aspect	Label 1	Label 2	Label 3	Label 4	Label 5	Label 6	Label 7	Label 8	Label 9	Label 10	Label 11	Label 12
Label size	Large	Large	Small	Large	Small	Large	Small	Small	Small	Large	Large	Small
Active ingredient[a]	Sentence	Sentence	Sentence **Bold**	Sentence **Bold**	Sentence **Bold**	UPPER CASE **Bold**	UPPER CASE **Bold**	UPPER CASE **Bold**	Sentence **Bold**	Sentence **Bold**	UPPER CASE **Bold**	Sentence
Brand name	Sentence	Sentence *Italic*	Sentence **Bold**	Sentence	Sentence *Italic*	Sentence	lower case *Italic*	lower case **Bold**	lower case **Bold**, *italic*	UPPER CASE **Bold**	UPPER CASE **Bold**	Sentence
Dosage form	Capsules	Cream	Tablets	Capsules	Cream	Suspension (child)	Suspension (child)	Tablets	Suspension (adult)	Suspension (adult)	Eye drops	Eye drops
Instruction (I): #[b] **of tabs/ caps/mL/ other**	#	Fingertip amount (FTA)	#	Words (such as ONE)	N/A	#	#	#	#	#	#	#
(I): Bold	N	Y ("1 FTA")	Y (#, approx. times of day)	Y (#, frequency, approx. times of day (table))	Y ("Apply")	Y (#, frequency (Child))	Y (#, volume)	Y (#, "Take")	Y (part of instructions)	Y (#, "Measure", approx. times of day)	Y (#)	Y (#, "left eye", approx. time of day)
(I): Bullets	N	Y	N	N	N	N	Y	N	N	Y (empty stomach definition)	N (indentation)	N
(I): Sentence	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
(I): Table	N	N	N	Y	N	N	N	N	N	N	N	N
(I): Prn	N	N	N	N	N	N	N	Y; max daily	Y; max daily	N	N	N
(I): Food	N	N	N	N	N	With food	With food	N	N	Empty stomach	N	N
(I): Hours	N	N	N	N	N	N	N	Y (interval)	Y (interval)	N	N	N
(I): Time of day	N	Y (approx. times of day)	Y (approx. times of day)	Y (approx. times of day, specific time range)	Y (approx. times of day)	N	Y (approx. times of day)	N	N	Y (approx. times of day)	Y (approx. time of day)	Y (approx. time of day)

[a] The research team agreed that active ingredient should be either Sentence case or UPPER CASE.

[b] # Refers to number of tablets or capsules or millilitres of suspension or drops included on the label, for example, 2 or 5 mL, respectively.

N/A = Not Applicable; Y = Yes; N = No.

2.6 Round 1

2.6.1.1 User testing method

The usability of the study labels was tested via the administration of a user testing questionnaire (UTQ). Outcome measures inherent in user testing include:

- ability to find the relevant information, and
- ability to understand the relevant information found

Demographically similar cohorts of 10 participating consumers (who were first recruited based on study inclusion criteria) user tested each label in accordance with user testing protocol.[2] A total of 40 consumers participated in Round 1, each participant user testing three unique labels in the following order:

1. A tablet or capsule label;
2. A suspension label; and
3. An eye drops or cream label.

As each participant evaluated three unique labels for three different dosage forms, questions regarding the "standard" information content were only asked for the first label evaluated. The "standard" information content was defined as information other than the directions for use and medicine name, and including the patient name, prescriber name, expiry date, date of dispensing, pharmacy name and address, and reference number, that were consistent on all labels. Two key points of information were used as proxies to evaluate the "standard" information content. These were questions on patient name and expiry date. For the remaining two labels, that is the suspension label and the eye drops or cream label, UTQ items were centred on the directions for use only. This process ensured that participants evaluated the "standard" information content only on the first label they were exposed to. Asking them to evaluate this information three times would have provided the researchers with no additional information regarding the content. It could have also led to participant study fatigue and adversely affected the overall quality of data collected. Furthermore, each cohort tested the "standard" information content in a different format, when comparing the initial label evaluated across the cohorts. This allowed for the impact of the label format on participants' ability to find and understand the relevant "standard" information content to be clearly evaluated.

The focus of the UTQ items on the latter two labels tested by each participant was the dosage and directions for use (not the "standard" information content). Overall, each participant evaluated the dosage and directions for use for three different dosage forms to ensure maximum feedback was received on all different dosage forms included in the study.

2.6.1.2 Clustering of labels for evaluation by each cohort

The three unique labels together formed a cluster of labels to be user tested by a participant. Within each cluster of labels evaluated (Table 3), labels were included that had the most diverse variations in their content and format, to ensure that there was no conditioning in participants' responses, and that all variations were appropriately evaluated. The broad factors considered when generating the label clusters were:

1. Label size (small and large);
2. "Standard" information content, that is, all information on the label except the directions for use and medicine name;
3. Active ingredient and brand name;
4. Font size; and
5. Formatting of instructions / directions for use.

Round 1 label clusters (Table 3) were then produced by process of elimination to avoid combinations that should ideally not be included in the same cluster. Where there were unavoidable clashes, priority was given to the combination considered to have more impact on appropriate and safe use of medicines. For example, a combination related to directions for use was given priority over active ingredient / brand name bolding. Dosage and directions for use were given the highest priority. This reflected the overarching study goal: the development and evaluation of labels that would lead to safe and appropriate use of medicines.

Table 3. Label clusters tested per demographically matched cohort in Round 1 user testing

Details	Cluster 1		Cluster 2		Cluster 3		Cluster 4	
Tablet / capsule label (Label A - first label to be user tested)	Label no.	1	Label no.	3	Label no.	4	Label no.	8
	Size[a]	Large	Size	Small	Size	Large	Size	Small
	"Standard" information content[b]	Single column	"Standard" information content	Two column	"Standard" information content	Single column	"Standard" information content	Single column
Suspension label (Label B)	Label no.	9	Label no.	6	Label no.	7	Label no.	10
	Size	Small	Size	Large	Size	Small	Size	Large
	"Standard" information content	Single column	"Standard" information content	Single column	"Standard" information content	Single column	"Standard" information content	Two column
Cream / eye drops label (Label C - last label to be user tested)	Label no.	11	Label no.	2	Label no.	12	Label no.	5
	Size	Large	Size	Large	Size	Small	Size	Small
	"Standard" information content	Two column	"Standard" information content	Two column	"Standard" information content	Two column	"Standard" information content	Two column

[a] Each cluster had a mixture of small and large labels to be tested by each cohort.

[b] Each cluster had a mixture of at least 2 different formats to display the "standard" information content (that is, the patient name, prescriber name, expiry date, date of dispensing, pharmacy name and address, and reference number).

2.6.1.3 User testing questionnaire development

A master core UTQ (Table 4) was developed by two research team members in order to evaluate the key outcome measures per label. Some questionnaire items were adapted from previous UTQs developed and used by members of the research team.[12-14]

Firstly, key points of information were determined for each label format and fictitious medicine. The key points formed the basis of the core UTQ items. The master core UTQ was then developed and adapted for each cluster to ensure that the appropriate UTQ items were administered per label.

To minimise order effects, a standardised order of labels for evaluation was implemented; that is:

1. A tablet / capsule label (Label "A"),
2. A suspension label (Label "B"), then
3. A cream / eye drops label (Label "C").

Questions, for example "Who does this medicine belong to?" and "What is the use-by date of this medicine?" pertaining to the "standard" information content found on each of the prescription label formats, were only asked for the first label that was user tested.

No prompting was permitted for the active ingredient UTQ item. This was intended to mitigate priming of participant responses across the three labels, and would better enable the investigation into the impact of formatting and presentation on understanding and differentiate between the active ingredient and brand name.

Table 4. Master user testing questionnaire

	Medicine information	**User testing question and relevant answer**	
Core UTQ items **LABEL A – TABLETS / CAPSULES**			
1	Name of patient	Q	Who does this medicine belong to?
		A	James Douglas
2	Active ingredient (A)	Q	What is the active ingredient found in this medicine*?* *Note: NO PROMPTING PERMITTED FOR THIS QUESTION*
		A	Myclofenac
3	Strength (A)	Q	How much of the active ingredient is in each tablet / capsule?
		A	75 mg
4	Expiry date	Q	What is the use-by date of this medicine?
		A	September 2021

<table>
<tr><th></th><th>Medicine information</th><th colspan="2">User testing question and relevant answer</th></tr>
<tr><td colspan="4">LABEL A – UTQ ITEMS CONTINUED</td></tr>
<tr><td>5</td><td>Dosage (A)</td><td>Q</td><td>Imagine you are taking Vipparoll for your pain. How much should you take and how often?

<u>Probe</u> (for Labels 1, 3, 8 which do not have the exact time of day specified; probe if specific times not mentioned by participant user testing Label 4):

- Imagine that your pain started at 9 am today. At what times would you take the tablets for the rest of today?</td></tr>
<tr><td></td><td></td><td>A</td><td>Label 1: 1 capsule 4 times a day

Label 3: 2 tablets in the morning, 2 tablets at midday, 2 tablets in the evening, 2 tablets at night

Label 4 (table): 1 capsule in the morning (7-9 am), 1 capsule at midday (12-1 pm), 1 capsule in the evening (4-6 pm) and 1 capsule at bedtime (9-11pm)

Label 8: 2 tablets every 6 hours when needed (for knee pain)</td></tr>
<tr><td>6a</td><td>Maximum dose (prn medicine) (A)</td><td>Q</td><td>Label 8 only: You have already taken 5 tablets so far today for your knee pain. How many more tablets can you still take today?</td></tr>
<tr><td></td><td></td><td>A</td><td>Label 8: 3 (maximum 8 tablets in 24 hours)</td></tr>
<tr><td>6b</td><td>Use as part of the overall treatment regimen for all conditions (testing table of doses) (A)</td><td>Q</td><td><u>GIVE SHOW CARD</u> (see Appendix 2)

Imagine you are already taking Medicine X 3 times a day, and Medicine Y at night, and Medicine Z twice a day.

When would you take this new medicine in relation to all of your other three medicines?

Probe (once the participant has verbalised their answer) –

<u>GIVE BLANK TABLE OF DOSES</u> (see Appendix 2): In this table, please write down when you would take each of these medicines.</td></tr>
<tr><td></td><td></td><td>A</td><td>
<table>
<tr><th></th><th>Morning
(7 to 9am)</th><th>Midday
(12 to 1pm)</th><th>Evening
(4 to 6pm)</th><th>Bedtime
(9 to 11pm)</th></tr>
<tr><td>X</td><td>1</td><td>1</td><td>1
(or bedtime)</td><td>1
(or evening)</td></tr>
<tr><td>Y</td><td></td><td></td><td>1
(or bedtime)</td><td>1
(or evening)</td></tr>
<tr><td>Z</td><td>1 + evening or bedtime</td><td>1 + bedtime</td><td></td><td></td></tr>
<tr><td>Myclofenac 75mg Capsules / Tablets Vipparoll</td><td>1 (Label 1, 4)

2 (Label 3)

N.B Label 8 prn therefore response will vary</td><td>1 (Label 1, 4)

2 (Label 3)

N.B Label 8 prn therefore response will vary</td><td>1 (Label 1, 4)

2 (Label 3)

N.B Label 8 prn therefore response will vary</td><td>1 (Label 1, 4)

2 (Label 3)

N.B Label 8 prn therefore response will vary</td></tr>
</table>
</td></tr>
</table>

	Medicine information	User testing question and relevant answer	
LABEL B – SUSPENSION			
7	Active ingredient (B)	Q	What is the active ingredient found in this medicine? *Note: NO PROMPTING PERMITTED FOR THIS QUESTION*
		A	Pentoampicillin (Labels 6, 7, 10) OR Myclofenac (Label 9)
8	Strength (B)	Q	How much of the active ingredient is in 5 mL?
		A	Labels 6, 7, 10: 500 mg Label 9: 75 mg
9	Dosage (B)	Q	Imagine you are giving / taking *Mixicillin / Vipparoll*. How much should you give / take and how often?
		A	Label 6: 9.5 mL three times a day with food (give to child) Label 7: 9.5 mL given in the morning, 9.5 mL in the afternoon and 9.5 mL at night, with food (give to child) Label 9: 10 mL when needed for pain and then if needed, take 10 mL after 6 hours Label 10: 5 mL taken in the morning and at night on an empty stomach
10a	Use in relation to food (B)	Q	Labels 6, 7: How should you give this medicine in relation to meals? OR Label 10: You normally have breakfast at 9 am. At what time could you take your morning dose of the medicine?
		A	Label 6, 7: Give with food Label 10: 8:30 am (30 minutes before food) OR 11 am (2 hours after food)
10b	Maximum dose *(prn medicine)* (B)	Q	Label 9 only: You have already taken 30 mL of the medicine so far today for your *pain*. How much more can you still take today?
		A	Label 9: 10 mL (maximum 4 doses in 24 hours; each dose = 10 mL)

	Medicine information	User testing question and relevant answer	
LABEL C – CREAM / EYE DROPS			
11	Active ingredient (C)	Q	What is the active ingredient found in this medicine? *Note: NO PROMPTING PERMITTED FOR THIS QUESTION*
		A	Ocylohydrosteroid (Labels 2, 5) OR Hypromethylmellose (Label 11, 12)
12	Strength (C)	Q	How much of the active ingredient is in the cream / eye drops?
		A	Labels 2, 5: 0.5% Labels 11, 12: 1%
13	Dosage (C)	Q	Imagine you are using this cream / eye drops for an itchy rash / dry eyes. How much should you use and how often? <u>Probe for Label 5</u> (no amount of cream specified): - How much would you apply each time?
		A	Label 2: 1 fingertip amount applied on the affected skin in the morning, at midday, in the evening, and at night Label 5: Apply on the affected skin in the morning and at night Labels 11 and 12: Put 2 drops into the left eye each night
14	Discard-by date (C)	Q	Labels 11, 12 only: If you opened these eye drops 2 weeks ago, what is its use-by date?
		A	Labels 11, 12: 2 weeks from today OR 14 days from today (Discard 28 days after opening it)

2.6.1.4 Semi-structured interview protocol development

The semi-structured interview component directly followed the completion of the UTQ. The objectives of the semi-structured interview component were to:

1. Explore consumer perspectives on the usability of the label formats they had tested;
2. Seek consumer feedback on areas of improvement needed for the labels to better support their medicine information needs and safe use of medicines; and
3. Explore consumer perspectives on the formatting of active ingredient and brand name information on current practice and tested label formats.

For this study, the interview protocol questions (Table 5) were adapted from previous research involving the user testing of over-the-counter medicine label formats,[15] and were mapped to each of the above objectives.

Table 5. Semi-structured interview protocol questions

Thinking back to the information on the prescription medicine labels you have just helped us test:

1. (Objective 1) Firstly, what are your overall thoughts about the label that you just helped us test, in terms of how easy / hard it is to read; and the information that is included on it?
2. (Objective 1) Looking at the information on the label, what do you think about the amount of information that it contains?
3. (Objective 1) What do you think about the layout of the information on the label?
4. (Objective 1) Thinking back to how you used the label to answer the questions before, what information was easy or difficult to find and/or understand?
5. (Objective 1, 2) From your point of view, how can we improve the label in the future to improve its readability and how well it is understood?
6. (Objective 1) After testing all three labels, what do you think about them overall?
7. (Objective 1) Comparing all three labels, what do you think about the size of the label?
8. (Objective 1) Focusing on the directions for use for these next two labels, what did you think about the information and how it was worded?
9. (Objective 1) What did you think about the formatting of the directions for use on these two labels?

(Once participant had been shown examples of existing prescription labels dispensed using Fred Dispense Software System)

10. (Objective 3) Here are some examples of labels which use a layout that you would normally see if you got a prescription medicine from a pharmacy.

    What do you think about the formatting of the active ingredient and brand name on these labels, compared to the ones you helped us test today?
11. (Objective 2) What do you think can be improved about the labels you helped us test today?
12. (Objective 2) Do you have any last comments on what else we can improve in the future regarding these labels?
13. Are there any other comments you would like to make?

2.6.1.5 Participant recruitment

Recruitment for the user testing interviews took place between December 2017 and January 2018. Recruitment was conducted via the use of online advertisements posted on the Gumtree website, distribution of hardcopy recruitment flyers, and snowballing.

Participants were recruited according to set inclusion / exclusion criteria, adapted from criteria used in previous user testing studies[8, 13, 14]:

Inclusion criteria

- 18 years or older
- Comfortable reading and speaking English in order to participate in the study without the need for assistance from a translator

Exclusion criteria

- The consumer was a health care professional (whether practising or retired) or who was employed in an occupation at the time of the study which primarily dealt with medicine information
- Self-reported significant visual impairment
- Significant cognitive impairment, which could affect their participation in user testing
- Participation in a user testing study in the 6 months prior to the present study

Interested participants contacted the research team. All relevant information relating to participant demographic characteristics, inclusion and exclusion criteria were assessed and recorded by the researchers as part of the initial contact with each participant. All collected demographic data were then re-confirmed on the day prior to commencing the user testing.

2.6.1.5.1 Principal sampling recruitment criteria for each cohort

Age, gender, and education were the main demographic factors which underpinned the sampling recruitment criteria (as per previous studies [8, 13, 14]).

There was a need to ensure an equal distribution of participants from each gender and education level (from not completing school to tertiary qualifications, where possible), and an even age distribution within each cohort. In each cohort, there was a minimum requirement of two consumers who were currently unemployed or retired, or did not routinely use written information / documents as part of the everyday practice of their employment.

Upon successful recruitment, each participant was allocated to user test a cluster of labels to ensure a spread of demographics between the cohorts.

2.6.1.6 User testing conduct: structure of the face-to-face interview session

Interviews were conducted at The University of Sydney School of Pharmacy in a room, commonly used for meetings or interviews. All interview sessions were conducted by either VT or SC, whom were both female researchers trained in user testing methods.

Data were collected via individual face-to-face interview sessions with participants, with three primary interview components:

(i) Administration of the core UTQ items for the first label (tablet or capsule);
(ii) Administration of core UTQ items pertaining to directions for use for the remaining labels (i.e. suspension; eye drops or cream); and
(iii) A semi-structured interview component.

The entire interview session was structured as follows:

a) Initial welcome and information provided about the study

- The interviewer confirmed details provided by the participant during recruitment, to confirm study eligibility
- Each participant was provided with the Participant Information Statement (Appendix 4) and Consent Form (Appendix 5) to sign (if consenting to participate), and given the opportunity to ask any questions about the study

b) Administration of the user testing questionnaire

- The participant was provided with an overview of the user testing process
- The participant was then provided with the first assigned label to be tested and given reading time (no restrictions)
- Once the label was read, the UTQ was administered for the first label
- After the first label had been user tested, two further labels were user tested in Round 1, with reading time given per label
- Results were recorded, as relevant to the following outcome measures: ability to locate the relevant information, and understanding of the located information

c) Semi-structured interview component

- The semi-structured interview was conducted as per the protocol (Table 5)

d) Additional demographic data collected, remuneration, conclusion of the interview session

- The participant was asked to complete an additional short demographics questionnaire, which also collated information about their subjective health literacy (Appendix 6). The questionnaire sought information on factors that could impact their ability to understand medicine information. The subjective health literacy questions have been administered in previous user testing studies,[8, 14] adapted from validated questions.[16]
- Remuneration was provided for consumer participation in the study at the completion of the session ($40 per participant).

2.7 Round 2 user testing

2.7.1 Similarities and differences between Round 1 and Round 2 user testing

The same study method from Round 1 was applied to Round 2 (Table 6). Where there were differences, these have been described in this section.

Round 2 recruitment and user testing were conducted in April 2018. A total of 20 consumers participated and each participant user tested four labels. An additional tablet label was evaluated per participant compared to Round 1.

The inclusion / exclusion criteria, recruitment strategy, and overall structure of the face-to-face interview session were consistent between Rounds 1 and 2. However, the UTQ items included in the master core UTQ from Round 1 were re-ordered where necessary and administered depending on the clustering of labels for evaluation by participants in Round 2 (Table 6).

Table 6. Similarities and differences between Round 1 and Round 2 user testing methods

Methods	Same for both Round 1 and Round 2	Details
Labels evaluated	X	12 labels evaluated in Round 1; 7 different labels evaluated in Round 2
Clustering of labels	X	Labels were clustered per round in accordance with their characteristics; therefore, a tailored clustering approach was applied
Number of labels user tested per cohort	X	3 labels were evaluated by each cohort in Round 1; 4 labels were evaluated by each cohort in Round 2
Number of cohorts	X	Number of cohorts recruited depending on the number of labels evaluated per round 4 cohorts in Round 1; 2 cohorts in Round 2
Total sample size	X	Round 1 – n=40 Round 2 – n=20
Recruitment protocol	✓	
Overall structure of the face-to-face session	✓	
Core UTQ items	✓	
Order of UTQ items	X	Re-ordering of core UTQ items between the user testing rounds depending on the label clusters
Core data analysis	✓	Data analysis processes adapted according to the labels evaluated

2.7.2 Labels evaluated in Round 2 user testing

Six labels were developed for Round 2 user testing based on the labels evaluated in Round 1 and the quantitative and qualitative user testing findings. Two label designs were developed per dosage form (tablets / capsules, suspension, cream / eye drops). Overall, half of the labels were two column format labels, and three were single column format labels, with a mixture of these label formats tested within each cluster. A 7th label was also proposed for evaluation by research team members at Canberra Hospital that was based on the Universal Medication Schedule (UMS) label format developed and evaluated by Wolf and colleagues.[3, 4] The aim of this label was to compare how the UMS compared with the study developed labels.

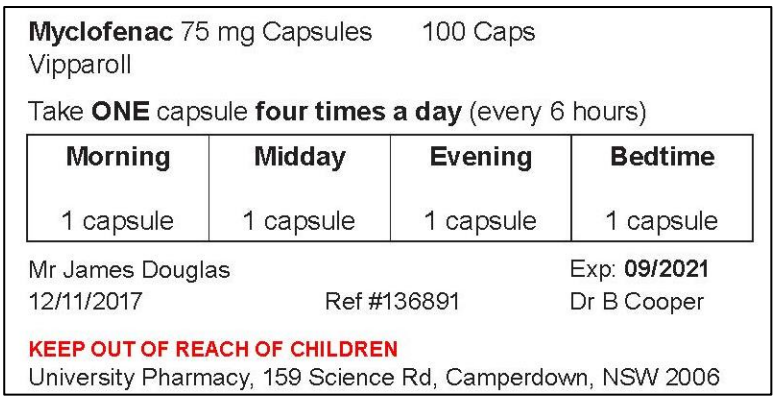
A total of 7 labels were therefore user tested in Round 2. The labels are shown below. Both small and large label sizes were evaluated, using the same label dimensions and corresponding font sizes for main directions (Table 7). However, the font size for the "standard" information content was slightly varied; Round 2 smaller labels used 7 or 8 point Arial font and larger labels had 8 or 9 point Arial font. The exception was the 7th label proposed by research team members for Canberra Hospital (Label 14B), which had a slightly increased label width to accommodate the main directions and table adapted from the UMS (dimensions 102 mm x 58 mm), 9 point Arial font size for the directions, and 8 or 9 point Arial font size for the "standard" information content.

Table 7. Label sizes and corresponding font sizes used on the study labels

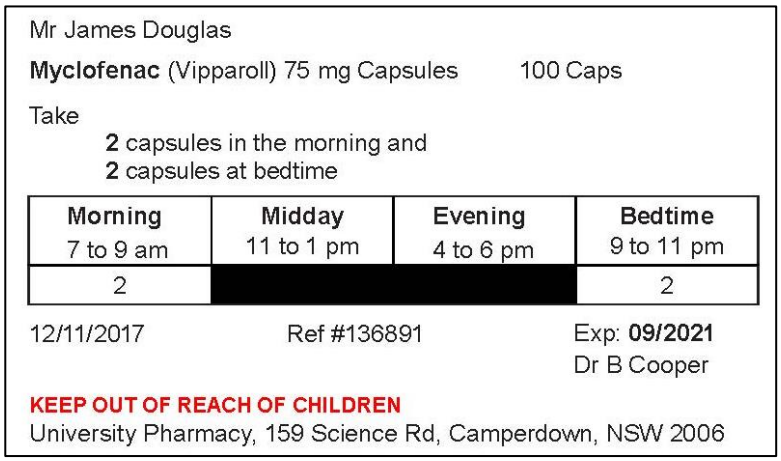
Label size	Length	Width	Arial Font size – directions	Arial Font size – "standard" information content	Comment(s)
Small – Rounds 1 and 2	80 mm	40 mm	Round 1: 8 point Round 2: 8 point	Round 1: 7 point Round 2: 8 point or 7 point	Standard label size (Fred)
Large – Rounds 1 and 2	102 mm	52 mm	Round 1: 10 point Round 2: 10 point	Round 1: 9 point Round 2: 9 point or 8 point	Dimensions suggested by graphic designer to accommodate larger font
Canberra label (UMS) – Round 2	102 mm	58 mm	9 point	9 point in general 8 point (keep out of reach of children in capitals and red font)	Increased width to accommodate for directions statement and UMS

Label 13
(80 mm x 40 mm)

Label 14A
(102 mm x 52 mm)

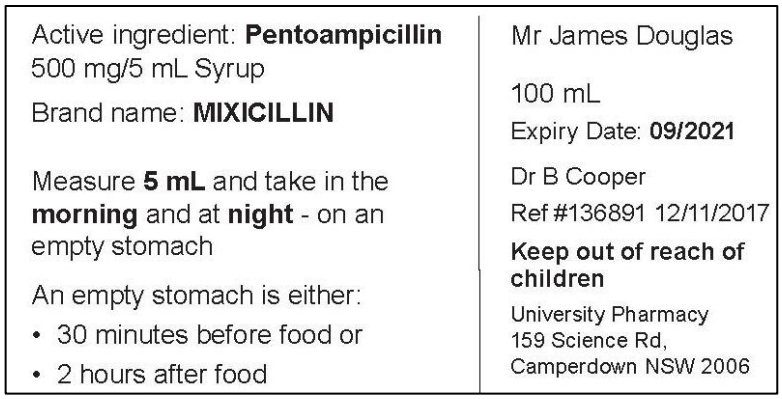


Label 14B
(102 mm x 58 mm)

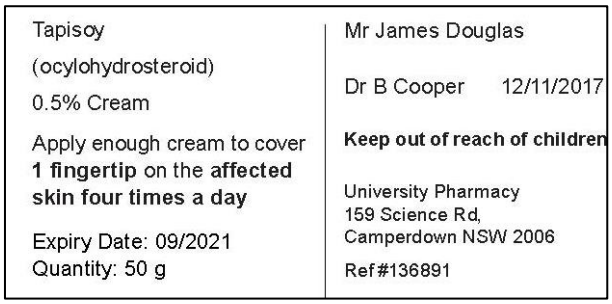


Label 15
(102 mm x 52 mm)

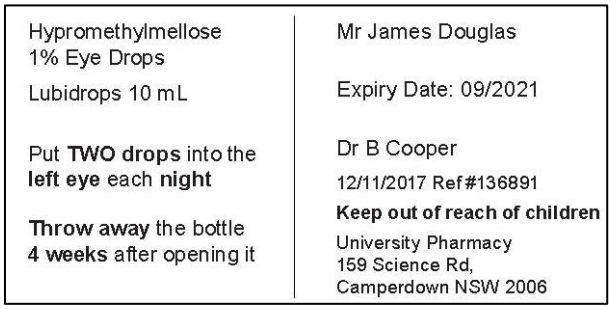
Label 16
(102 mm x 52 mm)



Label 17
(80 mm x 40 mm)



Label 18
(80 mm x 40 mm)



The primary label variables (Table 8) for Round 2 were:

1. Label size – small and large
2. "Standard" information content– Single column versus two column format
3. Active ingredient and brand name – order and positioning
4. Directions for use – content / expression

Table 8. Variations in labels evaluated in Round 2 of user testing

Label aspect	Label 13[a]	Label 14A	Label 14B[b]	Label 15	Label 16	Label 17	Label 18
Label size	Small	Large	Large	Large	Large	Small	Small
Single column or two column	Single column	Single column	Single column	Single column	Two column	Two column	Two column
Active ingredient	Sentence case	Sentence case **Bold**	Sentence case **Bold**	Sentence case **Bold**	Sentence case **Bold**	Lower case	Sentence case
Brand name	Sentence case **Bold**	Sentence case	Sentence case	Sentence case **Bold**	UPPER CASE **Bold**	Sentence case	Sentence case
Active ingredient presented first then brand name	N	Y	Y	N	Y	N	Y
Dosage form	Tablets	Capsules	Capsules	Suspension	Suspension	Cream	Eye drops
Instruction (I): #[c] of tabs/ caps/mL/other	#	Words	#	#	#	Fingertip (FT)	Words
(I): Bold	Y (#, interval, max daily dose)	Y (#, frequency, approx. times of day in table)	Y (#, approx. times of day in table)	Y (#, frequency, "with food")	Y (#, approx. times of day)	Y (FT, "affected skin", frequency)	Y (#, "left eye", "night")
(I): Bullets	N	N	N (indentation)	N	Y (empty stomach information)	N	N
(I): Sentence	Y	Y	Y	Y	Y	Y	Y
(I): Table	N	Y	Y	N	N	N	N
(I): Prn	Y	N	N	N	N	N	N
(I): Food	N	N	N	Y (with food)	Y (empty stomach)	N	N
(I): Hours	Y (interval)	Y (interval)	N	N (time interval in brackets)	N	N	N
(I): Time of day	N	Y (approx. times of day)	Y (approx. times of day, with specific time range)	N	Y (approx. time of day)	N	Y (approx. time of day)

[a] Every participant reviewed Label 13 as the last label to be user tested in each cluster for Round 2 – only the dosage-related questions were asked.
[b] Label 14B was the 7th label requested by Canberra Hospital for inclusion in Round 2 of the user testing.
[c] # Refers to number of tablets or capsules or millilitres of suspension or drops included on the label, for example, 2 or 5 mL, respectively.
Y = Yes; N = No.

2.7.3 Rationale for formatting of active ingredient and brand name for Round 2 labels

Four broad formatting changes relating to the active ingredient and brand name were implemented across the Round 2 labels.

Positioning of active ingredient and brand name – When examining both the qualitative and quantitative findings from Round 1, some participants preferred the brand name presented first, followed by the active ingredient. Participants reported to be accustomed to this; therefore, this order was trialled for testing on some of the Round 2 labels.

Sign-posting – Due to Round 1 labels' overall poor ability to support correct active ingredient identification, explicit specification of the active ingredient and the brand name on the label was included on two labels. It was hypothesised that this sign-posting of active ingredient and brand name would improve identification of the active ingredient by the participants.

Bolding – A mixture of bolding / non-bolding of active ingredient and brand name was used across the Round 2 labels to determine their impact on finding and understanding information.

Italics and upper case – The use of italics as a standalone formatting option was avoided as this resulted in misdirected signalling of which was the active ingredient.

From a medication safety perspective, bolding and use of upper case for the active ingredient in Round 2 in order to emphasise active ingredient, was avoided. This decision was due to participant misunderstanding that resulted from this formatting combination, supported by the qualitative findings of Round 1.

2.7.4 Further Round 2 label considerations

There were a few notable considerations for the labels developed for evaluation in Round 2 (Table 9).

Table 9. Round 2 user testing labels – summary of variables (and rationale for actioning in Round 2)

Characteristic(s)/ Variable(s)		
Tablets / capsules		
Label number for Round 2	**Label 13**	**Label 14A**
Label from Round 1 used as the foundation	**Label 8** (over Label 1 as can evaluate the prn aspect)	**Label 4** (has unique tabular format that was received positively)
Label size	**Small label**	**Large label**
Position of active ingredient and brand name	Brand name above; active ingredient below	Active ingredient above; brand name below
"Standard" information content	Single column • Expiry date and date of dispensing separated (participants found their close proximity as potential for confusion) • "Keep out of reach of children" in red and at the top of the label (participants liked this from the Fred labels) • Expiry date bolded (participants' suggested improvement)	Combination of single column formats, with improvements integrated from the user testing findings • Separating date of dispensing from expiry date • 100 Caps next to "title" (suggested improvement; similar to Fred label) • Expiry date bolded (participants' suggested improvement) • "Keep out of reach of children" in red and upper case (similar to Fred label)

Characteristic(s)/ Variable(s)		
Suspension		
Label number for Round 2	**Label 15**	**Label 16**
Label from Round 1 used as the foundation	**Label 6** (well-liked)	**Label 10** (well-liked; also integrates bullet points)
Label size	**Large label**	**Large label**
Position of active ingredient and brand name	Brand name above; active ingredient below State "Brand name: Mixicillin; Active ingredient: Pentoampicillin" (By doing it for the second label tested, we could see if this influences what participants state for the active ingredient on the first label without any influence, and also whether this influenced their response for the third label)	Active ingredient above; brand name below State "Brand name: Mixicillin; Active ingredient: Pentoampicillin" (see rationale in left hand column)
Content – active ingredient/brand name	• Suspension replaced with "Syrup" (the term suspension not user-friendly) • 500mg/5mL expressed instead as "Each 5 mL of the syrup contains 500 mg pentoampicillin" (a few participants found that medicine strength was difficult to understand in abbreviated form)	• Suspension replaced with "Syrup" (the term suspension not user-friendly) • 500mg/5mL maintained as a comparator to alternative expression in other suspension label
"Standard" information content	Single column • 100 mL placed next to "title" • Name and expiry date moved to above the line (suggested improvement) • Expiry date bolded • Pharmacy address smaller font (suggested improvement) • Keep out of reach of children moved to the bottom (suggested improvement)	Two column • The left hand column takes more space / prominence than right hand column (advocated by participants as the information on the left hand side perceived more important) • Expiry date and date of dispensing separated • Expiry date bolded • Smaller font size for pharmacy name

Characteristic(s)/ Variable(s)		
Cream / eye drops		
Label number for Round 2	**Label 17**	**Label 18**
Label from Round 1 used as the foundation	**Label 2 (cream)** (performed the best in the user testing component of the 2 cream labels)	**Label 12 (eye drops)** (bolding used on this label equated to the improvements suggested for Label 11)
Label size	**Small label** (instead of large like in Round 1 – pragmatic consideration due to size of actual product packaging in many cases)	**Small label**
Position of active ingredient and brand name	Brand name above; active ingredient below, in brackets and in lower case	Active ingredient above in sentence case; brand name below
"Standard" information content	Two column • Patient name and doctor name listed directly below one another • "Keep out of reach of children" in smaller font • Expiry date located in the left hand column (expiry date was cited as the only information from "standard" information content that would be looked at – as the information is product-specific, it is now co-located with other product-specific information) • Quantity now specified before "50 g" in the left hand column (product-specific information all together) • Reference number at the bottom of label (people did not understand what this number meant)	Two column • "10 mL" located with brand name • Date of dispensing and reference number moved further down label and printed in smaller font size (less important information)

2.7.5 Clustering and ordering of labels for evaluation in Round 2

Similar to Round 1, there were three label formats (and one additional label) that formed each cluster. Each cohort of 10 participants evaluated one cluster of three labels in Round 2. The order in which labels were evaluated was revised for Round 2 to ensure that the two column versus single column label format for the "standard" information content (patient name and expiry date) could be evaluated (Table 10).

The order of evaluation per cluster was:

- Cluster 5: Cream label, Suspension label, Capsule label, Tablet label
- Cluster 6: Capsule label, Suspension label, Eye drops label, Tablet label

Both cohorts in Round 2 evaluated Label 13 in order to allow for directions for "as required" use to be evaluated, including maximum dose information.

Table 10. Label clusters for Round 2 user testing per demographically matched cohort

Details	Cluster 5		Cluster 6	
First label tested	Label number	17	Label number	14B
	Size[a]	Small	Size	Large
	Dosage form	Cream	Dosage form	Capsules
	"Standard" information content[b]	Two column	"Standard" information content	Single column
	Active ingredient or brand name first	Brand	Active ingredient or brand name first	Active
Second label tested	Label number	16	Label number	15
	Size	Large	Size	Large
	Dosage form	Suspension	Dosage form	Suspension
	"Standard" information content	Two column	"Standard" information content	Single column
	Active ingredient or brand name first	Active	Active ingredient or brand name first	Brand
Third label tested	Label no.	14A	Label no.	18
	Size	Large	Size	Small
	Dosage form	Capsules	Dosage form	Eye drops
	"Standard" information content	Single column	"Standard" information content	Two column
	Active ingredient or brand name first	Active	Active ingredient or brand name first	Active
Fourth label tested	Label no.	13		
	Size	Small		
	Dosage form	Tablets		
	"Standard" information content	Single column		
	Active ingredient or brand name first	Brand		

[a] Each cluster evaluated 2 large labels and 2 small labels.

[b] Each cluster had a mixture of at least 2 different "standard" information content. "Standard" information content refers to patient name, prescriber name, date of dispensing, expiry date, reference number, pharmacy name and address. In particular, the first label evaluated in each cohort had a different format so that the "standard" information content (patient name and expiry date) could be evaluated on each of the key format types.

2.8 Data analysis

With the exception of one interview, all remaining interview sessions (n=59) were audio recorded with consent from participants. One participant in Round 1 did not consent to audio recording. Field notes were taken by the interviewer in lieu of the audio recording (SC). The field notes were reviewed and finalised upon interview completion and used for data analysis.

2.8.1 Quantitative data analysis

All audio recordings were reviewed by at least two members of the research team. Responses to each UTQ item were transcribed verbatim in preparation for analysis. The quantitative component of user testing, that is, participant responses to each UTQ item, were coded against the primary outcome measures: ability to find the relevant information and ability to understand the information that was found.

The industry standard success criteria for user testing of patient information leaflets (PILs) implemented in the UK is:

"90% of the test participants are able to find the information requested within the PIL, of which 90% can show that they understand it."[1(p.6)]

These criteria were used in this study to determine an overall measure of label performance. Therefore, when adapting these criteria for each round of user testing (and applying the criteria to the quantitative results), there was a requirement that:

- a **minimum** of **9/10 participants** were able to **find the information**, and
- of these, **9 participants** would have had to demonstrate **complete understanding** for each key point of information.

Therefore, more than 8/10 participants were expected to be able to find **and** understand the key information.

Each response was coded against the model answer in accordance with the master core UTQ. Finding and understanding the relevant information were treated as two distinct outcome measures and coded separately. Data were coded by two different research team members for each participant to ensure validity and reliability of response coding. Responses that did not fully correspond with the master core UTQ and / or the coder had any queries were flagged by the research team member. Such responses were then recoded by a researcher with extensive experience in user testing methods, and any further coding discrepancies discussed and resolved via consensus with another researcher.

For the administration of the UTQ item that required participants to plan a daily dosing schedule in Round 2 of the user testing, the coding framework remained the same in both Round 1 and 2 for Medicines X, Y, and Z (presented on the show card). However, when asked with regards to the Round 2 myclofenac labels (Label 14A and 14B):

- Some participants did not indicate a specific time that they would take the dose on the actual table itself. If the proposed dosing schedule corresponded with the dosing table on the label, this was coded as correct.
- However, if the participant chose to specify a particular time when taking the dose – for instance with Label 14A, a 6-hour interval between dose was considered appropriate spacing of the dose. This was because the label explicitly stated 6 hours as the dosing interval. Any deviation from this was coded as inappropriate for the purposes of this study.

2.8.2 Analysis of participant responses to probe questions

Two probe questions (1] related to the directions for use in a scenario where pain was experienced at 9 am; and 2] clarification as to how much cream to apply) were asked. Analysis of participant responses given for these probe questions was adapted from the data analysis process completed in a previous similar study.[12] This involved inductive analysis of the responses, and the subsequent development and refinement of a coding framework. Consideration was given to the intended meaning of the directions for use on the label and how the directions were then applied.

2.8.2.1 Round 1

A coding framework was developed for the three labels (Labels 1, 3 and 8) that did not include a dosing table with explicit times stated as to when doses were to be taken (Table 11). This allowed for comparison with the responses provided by the participants who evaluated Label 4 (with the dosing table) to help elicit the impact of how dosage information was conveyed.

Table 11. Broad coding framework for the probe question on dosage for the tablet / capsule labels (Round 1)

<table>
<tr><th>Label</th><th>Dosage expression</th><th>Dosage specified</th><th>Appropriateness threshold for accepted response coding</th><th>Comments / other considerations</th></tr>
<tr><td>1</td><td>Frequency of doses per day</td><td>“Take 1 capsule four times a day”</td><td>All dosing intervals were 4 to 6 hours apart</td><td></td></tr>
<tr><td>3</td><td>Approximate times of day for dosing</td><td>“Take
2 tablets in the morning
2 tablets at midday
2 tablets in the evening
2 tablets at night”</td><td>All dosing intervals were 4 to 6 hours apart</td><td></td></tr>
<tr><td>4</td><td>Tabulated dosing schedule with explicit times</td><td>“Take ONE capsule four times a day”
<table><tr><th>Morning
(7 to 9am)</th><th>Midday
(12 to 1pm)</th><th>Evening
(4 to 6pm)</th><th>Bedtime
(9 to 11pm)</th></tr><tr><td>1 capsule</td><td>1 capsule</td><td>1 capsule</td><td>1 capsule</td></tr></table></td><td>Acceptable if stated that they would take during the specified time-frames as per the table</td><td>Note: Dosing intervals less than 4 to 6 hours could not be deemed inappropriate as the table information could be interpreted as dosing intervals of less than 4 to 6 hours</td></tr>
<tr><td>8</td><td>Explicit dosing interval</td><td>“Take 2 tablets every 6 hours, when needed for knee pain
Do not take more than 8 tablets in 24 hours”</td><td>6-hour dosing interval adhered to</td><td></td></tr>
</table>

2.8.2.2 Round 2

Coding of participant responses in relation to Labels 14A and 14B evaluated in Round 2 were adapted from the coding framework used in Round 1:

- As Label 14A stated an explicit dosing interval of 6 hours, responses were considered appropriate where a 6-hour dosing interval was adhered to
- As Label 14B also had a tabulated dosing schedule with explicit times (similar to Label 4), it was also acceptable if the participant stated that they would take the medicine during the specified time-frames as per the table

2.8.3 Semi-structured interview analysis

All semi-structured interview parts of the face-to-face interview sessions were transcribed verbatim. The transcripts were then systematically checked against the audio recording to ensure their accuracy.

All finalised transcripts were thematically analysed,[17] with the aid of matrix displays where appropriate.[18] Themes and subthemes were inductively derived and grouped.

For the purposes of this report, findings of key relevance to the labels evaluated in the study are presented. Targeted findings that supported or contradicted the quantitative findings were of particular interest.

3. Results

3.1 Round 1

3.1.1 Participant demographics

Overall, a total of 40 participants took part in Round 1 of the user testing. Across all four clusters, there were approximately equal numbers of males and females, as well as participants born in Australia and other countries (Table 12). Most participants spoke English as their main language at home, and there were no more than four participants per cluster who had attained a Bachelor's degree or higher.

Table 12. Summary of participant demographics – Round 1 user testing

Demographic		Cluster 1 (n=10)	Cluster 2 (n=10)	Cluster 3 (n=10)	Cluster 4 (n=10)	Total (n=40)
Gender	Male	5	5	5	4	19
	Female	5	5	5	6	21
Age (years)	18-29	5	5	4	4	18
	30-49	4	3	5	5	17
	50-69	1	2	1	1	5
Highest level of education attained	School certificate (Year 10) or below	0	1	0	0	1
	Higher School Certificate (Year 12) or college qualification	6	5	7	6	24
	Bachelor's degree or higher	4	4	3	4	15
Regular use of written information as part of occupation	Yes	7	8	5	6	26
	No	3	2	5	4	14
Main language spoken at home	English	7	7	7	7	28
	Other	3	3	3	3	12
Country of birth	Australia	5	6	6	4	21
	Other	5	4	4	6	19

With respect to self-reported understanding of health / medicines-related information, 37 participants stated that they were extremely or quite confident with completing medical forms by themselves (Table 13). Three quarters of the participants (30/40) cited that they required little or no assistance with reading written medicine information. Only five participants reported difficulties in learning about their health or medicines more than a little of the time (Table 13).

Table 13. Round 1 participants' self-reported understanding of health and/or medicine-related information (n=40)

Question		Participant responses Number of participants				
		1	2	3	4	5
1. How confident are you filling out medical forms by yourself?[a]	Cluster 1	0	0	0	3	7
	Cluster 2[b]	0	1	0	4	4
	Cluster 3	0	0	1	3	6
	Cluster 4	0	0	0	4	6
2. How often do you have someone help you read written medicine information?[c]	Cluster 1	3	4	1	2	0
	Cluster 2	9	0	1	0	0
	Cluster 3	5	3	2	0	0
	Cluster 4	5	1	3	1	0
3. How often do you have problems learning about your medical condition or medicines because of difficulty reading and understanding written information? [c]	Cluster 1	7	0	2	1	0
	Cluster 2	7	2	1	0	0
	Cluster 3	5	4	1	0	0
	Cluster 4	7	3	0	0	0

[a] The scale of 1 to 5 denotes: 1=not at all, 2=a little, 3=somewhat, 4=quite, 5=extremely.

[b] One participant stated that they have never filled one out.

[c] The scale of 1 to 5 denotes: 1=none of the time, 2=a little of the time, 3=some of the time, 4=most of the time, 5=all of the time.

3.1.2 Label reading times

Overall, the average reading time per label ranged between 14.6 seconds (Label 5) and 26.3 seconds (Label 10).

3.1.3 Round 1 user testing – quantitative findings

When examining the findings from the user testing of all 12 label formats in Round 1, medicine strength and dosage were generally well found and understood. At least 8/10 participants found **and** understood the relevant information on the label (Table 14). In contrast, identifying the active ingredient on the label varied significantly between the labels (Section 3.1.4).

Table 14. Summary of Round 1 user testing findings (quantitative)[a]

	Tablet / capsule labels (A) Number of participants				**Suspension labels (B) Number of participants**				**Cream labels (C) Number of participants**		**Eye drops labels (C) Number of participants**	
Label cluster	1	2	3	4	2	3	1	4	2	4	1	3
Label	Label 1	Label 3	Label 4	Label 8	Label 6	Label 7	Label 9	Label 10	Label 2	Label 5	Label 11	Label 12
Found (n) Understood (n)	F[b] U[b] (n=10)	F U (n=10)	F U (n=10)	F U (n=10)	F U (n=10)	F U (n=10)	F U (n=10)	F U (n=10)	F U (n=10)	F U (n=10)	F U (n=10)	F U (n=10)
User testing questionnaire (UTQ) item												
Name of patient	10 10	10 10	10 10	9 9								
Active ingredient	7 7	2 2	4 4	3 3	3 3	3 3	7 7	5 5	3 3	5 5	9 9	8 8
Strength	10 10	10 10	9 9	8 8	10 10	10 10	10 10	10 10	10 10	8 8	9 8	9 8
Expiry date	10 10	10 9	10 10	10 10								
Dosage	10 10	10 10	10 10	10 10	10 9	10 10	10 9	9 9	10 10	10 9	10 10	10 10
Testing of dosing table[c] (appropriate dosing schedule)	7	8	7	6								
Use in relation to food					10 10	10 10		10 10				
Maximum dose *(prn medicine)*				10 8			10 10					
Discard-by date[d]											10 9	10 10

[a] Each participant evaluated 3 different labels (comprising 1 label cluster) in the following order: 1) A tablets / capsules label; 2) A suspension label and; 3) A cream or eye drops label.

[b] F = Found (number who found the relevant information on the label); U = Understood (number who understood the relevant information found).

[c] This question involved a show card which was provided to the participant. For this question, the participant was required to plan a daily dosing schedule for three hypothetical medicines they were currently taking, plus the new medicine corresponding to the label that was being tested. As dosage was addressed in a previous question, responses were coded using the dosing schedule. Therefore, the number of participants denotes the number who were able to plan an appropriate dosing schedule.

[d] This refers to discarding 28 days after opening the eye drops.

Tablet / Capsule labels

When examining the performance of the tablet / capsule labels, almost all participants could find and understand the patient name and the expiry date (Table 14). These key points of information constituted the "standard" information content that was included across all labels. For the participant who did not demonstrate complete understanding of the expiry date, this was due to an incorrect interpretation of the month; October 2021 was stated as opposed to the correct answer of September 2021 (expressed as 09/2021 on the label).

With respect to the medicine strength, 3/40 participants could not find and understand this information (Table 14). Interestingly, one participant who evaluated Label 8 incorrectly commented that tablet size ("how big the tablets are") was specified but not the strength.

Although all participants were able to locate the maximum dose (included on Label 8), two participants did not demonstrate complete understanding of the maximum daily dose (Table 14). Based on the given scenario, three more tablets could still be taken that day. However, both participants stated that only two more tablets could be taken as the participant either erred on the side of caution or attempted to complete the calculation factoring in the dosing interval of 6 hours (and as implied from their response, not in a 24-hour day).

For the question that required participants to plan a daily dosing schedule for four medicines, that is, medicines X, Y, Z presented on a show card and the medicine corresponding to the label being evaluated (Vipparoll), 28/40 participants were able to plan appropriate dosing schedules. Of the 12 participants who planned inappropriate schedules, in consideration of the *a priori* coding framework, the key reasons were:

- Incorrect dosing time –
    - Medicine X, to be taken three times a day, was specified in the dosing schedule by five participants to be taken in the morning, evening, and bedtime;
    - Medicine Y, to be taken at night, was specified by one participant to be taken at midday in the dosing schedule;
- Incorrect dosing interval –
    - The two doses of Medicine Z (to be taken twice a day) was specified by three participants to be taken too close together
- Vipparoll dosing issues –
    - Label 4- One participant missed the evening dose
    - Label 8- Two participants had issues observing the 6-hour dosing interval

Suspension labels

Overall, the suspension labels exhibited better performance in comparison to the tablet / capsule, cream and eye drops labels. At least 9/10 participants were able to find and understand the medicine strength, dosage, as well as use in relation to food and maximum dose (as per the corresponding label) (Table 14). Label 7 was the best performing label out of the four suspension labels (excluding the active ingredient UTQ item).

Cream labels

Aside from the active ingredient identification, both cream labels performed well. Notably, as this was a non-solid dosage form, the strength of the cream proved problematic for 2/10 participants evaluating Label 5 (Table 14). Both specified that the amount of active ingredient in the cream was 25 g and 50 g, respectively, rather than 0.5% as specified on the label. The cream quantity indicated on the label was 50 g, which indicated confusion between the medicine strength and total amount of cream.

Eye drops labels

Of all the labels, the eye drops labels performed best in enabling participants to correctly understand what the active ingredient in the medicine was. However, of those who could correctly locate the medicine strength for the eye drops, two participants were not able to adequately understand the information (Table 14). They expressed that they did not understand what the 1% meant.

For the discard-by date, one participant miscalculated and stated that the discard-by date was 16 days from the date of the interview (rather than 14 days) (Table 14).

3.1.4 Active ingredient versus brand name formatting

Collectively, only 4 of the 12 labels supported more than 5/10 participants in correctly identifying the active ingredient on the label. Less than 5/10 participants could correctly identify the active ingredient for half of the labels evaluated as part of the user testing in Round 1 (Table 15).

Label 1 performed best in terms of correct active ingredient identification when examining the findings for the tablet / capsule labels in particular (which had the same active ingredient and brand name specified on the label itself).

As evidenced by the findings from user testing of Clusters 1 and 3, the proportion of participants finding and understanding the active ingredient were higher for the eye drops labels in comparison to the label evaluated immediately prior (N.B. the eye drops labels were always the last label of the three in a cluster to be evaluated by the participants). The active ingredient on both eye drops labels was consistently correctly identified. Aside from the eye drops labels, a trend was observed where labels that presented the active ingredient in bold and upper case appeared to poorly support active ingredient identification (Table 15).

Table 15. Summary of Round 1 user testing findings for the active ingredient UTQ items

Dosage form	Label	Cluster	Active ingredient (AI) formatting Brand name (BN) formatting	No. found and understood active ingredient[a]	Comments and considerations for development of labels for Round 2
Tablets / capsules	1	1	AI, Sentence[b] BN, Sentence	7	Label 1 did not utilise any bolding /upper case / italics. Therefore, need to consider whether bolding, uppercase or italics have an impact
	3	2	AI, Sentence **Bold** BN, Sentence **Bold**	2	Both active ingredient and brand name have the exact same formatting. Therefore, people would have needed to rely on other rationale(s) other than formatting to distinguish between the two (for example brand name accustomed to being at the top of the label)
	4	3	AI, Sentence **Bold** BN, Sentence	4	Bolding of active ingredient only may explain why it was commonly mistaken as the brand name
	8	4	AI, UPPER CASE **Bold** BN, lower case **Bold**	3	Upper case bolding of active ingredient may have incorrectly signalled that it was the brand name instead
Suspension	6	2	AI, UPPER CASE **Bold** BN, Sentence	3	Upper case bolding of active ingredient may have incorrectly signalled that it was the brand name instead
	7	3	AI, UPPER CASE **Bold** BN, lower case *Italic*	3	Upper case bolding of active ingredient may have incorrectly signalled that it was the brand name instead
	9	1	AI, Sentence **Bold** BN, lower case **Bold**, *italic*	7	Formatting of Label 9 may have not made an impact (or less of an impact) on the correct active ingredient identification, as participants may have chosen the same answer for the active ingredient for both Labels 1 and 9 (considering that both utilised the same hypothetical brand name and active ingredient and were in the same cluster for evaluation)
	10	4	AI, Sentence **Bold** BN, UPPER CASE **Bold**	5	As the brand name was stated in upper case, this may explain why there is a slightly higher proportion who got this correct compared to labels where only the active ingredient was specified using upper case bold font
Cream	2	2	AI, Sentence BN, Sentence *Italic*	3	One explanation for poor active ingredient identification for this label, as reported by a participant, was that the brand name Tapisoy was in italics so thought it was the active ingredient, and that brand name would usually be on top
	5	4	AI, Sentence **Bold** BN, Sentence *Italic*	5	Tapisoy may have been perceived to be the active ingredient as it was presented in different "font", that is italics
Eye drops	11	1	AI, UPPER CASE **Bold** BN, UPPER CASE **Bold**	9	Both active ingredient and brand name have the same formatting within each label therefore the technical jargon-like nature of the active ingredient likely to be the deciding factor for underpinning the choice between active ingredient and brand name
	12	3	AI, Sentence BN, Sentence	8	

[a] < 5 found and understood = cell highlighted in red; 5 found and understood = cell highlighted in yellow; > 5 found and understood = cell highlighted in green.

[b] Refers to Sentence case.

3.1.5 Semi-structured interview findings: determining the active ingredient and the brand name – participants' thought processes

Overall, with the exceptions of the eye drops labels (Label 11 and 12), Label 1 (tablets) and Label 9 (suspension), the labels generally poorly supported participants in determining which was the active ingredient and which was the brand name. When asking participants to elaborate on how they differentiated between the two, several contributing factors and considerations were raised. These were largely centred on processing of formatting differences that were observed between the "active ingredient" and the "brand name" (Table 16).

Table 16. How participants determined the active ingredient[a] and the brand name (with no prompting by the interviewer)

Self-reported contributing factor	Details
1. Co-location of active ingredient and strength	• Assumption that the medicine strength was written next to the active ingredient itself • Incorrectly thought "tapisoy" was the active ingredient because 0.5% cream was written before it
2. Stating brand name first then active ingredient is current practice	• Thought that brand name would come first before the active ingredient on the label • Believed that normal convention is to have brand name first then active ingredient below • Expected "pentoampicillin" to be the brand name as it was in bold and at the top (that is, combination of formatting and positioning) • Believed that active ingredient(s) were normally included in brackets
3. Brand name normally presented in bold	• Brand name in bold; with active ingredient under the brand name • Bolded "myclofenac" made the participant incorrectly think that it was the "title", that is, brand name (Label 4)
4. Upper case and / or bolding together indicative of brand name	• Thought the brand was in upper case • Bolded, upper case "pentoampicillin" (Label 6) hence incorrectly thought it was the brand name • Used to medicine names (brand names) being in bold and upper case • Sentence case used for "Myclofenac" with lower case for "vipparoll" incorrectly signalled that myclofenac was the brand name (Label 9)
5. Italics signalled it was the active ingredient	• "Tapisoy" was in italics so incorrectly thought it was the active ingredient
6. Scientific-sounding name	• "Vipparoll" / "Lubidrops" did not sound like an active ingredient, that is, anticipating the active ingredient to be jargon-like / technical language • Chose the hardest one to pronounce as the active ingredient ("pentoampicillin") • "Tapisoy" did not sound like an active ingredient; "ocylohydrosteroid" has the word steroid in it, therefore understood to be the active ingredient
7. Missed brand name	• Thought "hypromethylmellose" was the active ingredient – there did not seem to be an active ingredient anywhere so thought that they (active ingredient and brand name) were one and the same
8. Guesswork	• Participants guessed

[a] All labels were formatted such that the active ingredient was stated on the first line; strength and dosage form were presented together following on from the active ingredient (to the right or just below) and then brand name was included separately on the line below.

3.1.6 Applied understanding of medicine dosages

Pain scenario and dosing with reference to the tablet / capsule labels

Following on from the dosage question in the core UTQ, participants were asked an additional probe question for each tablet / capsule label to determine how they proposed to take the medicine for the remainder of the day if their pain started at 9 am. Participant responses were evaluated using the coding framework (Section 2.8).

The largest proportion of participants who nominated an appropriate dosing schedule with appropriate dosing intervals, was observed for Label 8, which stated an explicit dosing interval of 6 hours (Table 17). Doses were appropriately spaced by 7 and 9 participants if the label stated the frequency of doses per day (Label 1) or a specific dosing interval (Label 8), respectively (Table 17).

Table 17. Coding of responses to the probe question regarding dosage and pain scenario for tablets / capsules from Round 1 (n=10 participants per label)

Label	Appropriate dosing intervals	Inappropriate dosing interval(s)		
		Shorter dosing interval(s)	Longer dosing interval(s)	Shorter and longer dosing intervals
1	7	3	0	0
3	3	6	0	1
8	9	0	1	0
4[a]	7/10 correctly cited the dosing times in accordance with the dosing table when asked the UTQ item regarding dosage 3/10 participants were further probed, and correctly nominated dosing times in line with the dosing table			

[a] N.B. Label 4 contained the table with specific times at which the doses were to be taken. Therefore, the probe question was only asked if the participant did not specify times at which they would take the medicine as part of their first response.

For labels without explicit intervals or times (Labels 1 and 3), planned dosing intervals varied; the time between doses varied the most for Label 3 (range 1.5 to 7 hours). However, of those who designated appropriate dosing schedules as per the coding framework, more participants indicated that they would evenly space dosing intervals for the medicine in response to Label 1 (n=6) than Label 3 (n=3).

For Label 3, where approximate times of day for dosing were stated on the label (that is, morning, midday, evening and at night), 3/10 participants stated appropriate and evenly spaced dosing times (Table 17). Two of these participants explained that they were consciously trying to ensure a 4-hour gap between the doses.

> *"I think just because there's 4 different occasions during the day that you're meant to be taking it, and by my calculation, that was 4 hours in between each of them." (Participant (P) 2 (P2))*

In general, participants attempted to adhere to the approximate times of day stated on the label and proposed corresponding specific times of day. The gap between the morning and midday dose or evening and night dose were commonly the shorter dosing interval. The time at which the "evening" dose was proposed to be taken ranged from 1 pm to 7 pm; the majority indicated they would take it at 5-7 pm. The range of times specified at which the "night" dose would be taken was between 2:30 pm to midnight.

With regards to Label 8, the vast majority observed the 6-hour dosing interval as specified on the label. The one participant who did not designate an appropriate dosing regimen ignored the instructions on the label, stating that they would take the first dose of the tablets in advance of the pain (despite the label stating that it should be taken when needed for knee pain).

Amount of cream to be applied

Participants evaluating Label 5 (where no amount to apply had been specified) were asked how much of the cream they would apply as a result of the directions "Apply the cream on the affected skin in the morning and at night".

Participants acknowledged that the label did not specify an amount of cream to be applied. However, several commented that the amount they would apply would depend on the size of the rash. Whilst a few commented that they would apply an appropriate amount to cover the area, others said that they would apply a thick layer.

> *"So, say if it was like a large rash on the top of the hand or something like that, I'd just put like a thin layer over it. Yeah, I guess common sense would prevail." (P7)*

> *"I'd apply enough to cover the whole area, but not enough that it's visible after I rub it in. So like just a slight layer." (P24)*

> *"It's hard to measure but I would go for quite a thick dose. But I have no instruction on how, so it's hard to tell. But if I were in the case of using cream with infection, I like to put thick amounts." (P18)*

Several participants said that they would apply the cream and monitor its effects, with the observed effect then determining further action; for instance, an adjustment of the amount of cream to be applied.

To probe into the participants' understanding of "1 fingertip amount" (Label 2), participants were asked to explain what a fingertip amount meant to them or how they would measure this if at home.

In general, participants either intended to squeeze or dab the cream onto the fingertip and ensure that there was sufficient cream to cover the area or said they would just squeeze a small amount onto the fingertip.

> *"So it can either be two ways, where it's just a dab on the fingertip or it's actually worth a fingernail, so say a pea-sized amount that you squeeze on your hand. But I am going to say dipping my finger in it – that covers." (P34)*

Interestingly, one participant queried what area the "fingertip" corresponded to.

> *"I mean that's a little confusing I suppose. I'd probably try to seek clarification, but I'm not sure whether it's say the top of the finger or whether it's the fingerprint area, and that's you know a huge difference in terms of size. When I think of fingertip, I think of the very tip of the finger, rather than the fingerprint." (P17)*

3.1.7 Performance of Round 1 user testing labels with respect to industry standards

When comparing the performance of each label against industry testing standards, and excluding the data pertaining to active ingredient identification and dosing schedule tabulation, 8/12 labels met the requirements in relation to all UTQ items (Table 18). For the remaining 4 labels, medicine strength was the common UTQ item that led to the label not meeting industry standards. Only Label 11 met the industry standard for participants finding and understanding the active ingredient.

Table 18. Comparison of Round 1 user testing findings to industry standards

Dosage form	Label	Met industry requirements for all UTQ items[a]	UTQ item(s) responsible for not meeting minimum requirements
Tablet / Capsule	1	✓	
	3	✓	
	4	✓	
	8	×	Medicine strength Maximum dose (*prn medicine*)
Suspension	6	✓	
	7	✓	
	9	✓	
	10	✓	
Cream	2	✓	
	5	×	Medicine strength
Eye drops	11	×	Medicine strength
	12	×	Medicine strength

[a] UTQ data for active ingredient identification and dosing schedule tabulation have been excluded.

3.1.8 Semi-structured interview findings: label feedback and perceived improvements required

Participant perspectives on the design, content, and wording used on the labels evaluated in Round 1 user testing

The feedback provided by the participants were categorised into “likes” and “dislikes” under the broad themes of design, content and wording of the labels. Table 19 provides the detailed findings for labels evaluated in Round 1, excluding “standard” information content feedback. Table 20 summarises the participants’ suggestions for improvements.

Table 19. Participant perspectives on the design, content, and wording of the labels evaluated in Round 1 user testing (excluding "standard" information content feedback)

Tablets / capsules				
	Label 1 (Cluster 1)	**Label 3 (Cluster 2)**	**Label 4 (Cluster 3)**	**Label 8 (Cluster 4)**
Design	Likes: • Gaps between information / white spacing – clear • Single column format Dislikes: • Bolding – lack of bolding; more people disliked lack of bolding than those who didn't mind / liked its absence • Queried location of 100 caps on label – just dropped in the middle • Expiry – location of expiry close to other date – confusing	Likes: • Bolding – bold dose and time of day liked • List layout – easier, can follow from top to bottom, easier to understand / remember Dislikes: • Design – busy • Columns – not as clear as single column for processing information; layout and size made it harder to process • Two columns more difficult to read; confusing • Font – small writing • Bolding – confusing that both active ingredient and brand are in bold - which is significant? • Bolding – too much overall	Likes: • Layout - clear • Table format – clear and stands out; more detailed; knows roughly the dosing interval as well • Table format – easier to read; easy to understand • Bolding – good; dose and frequency in sentence and morning, midday, evening, bedtime in table • Bolding – liked for product name / brand at top (many people thought myclofenac was brand) • Bold & capitals - 'ONE' in direction good – stands out	Likes: • Bolding – dose instruction in bold • Font good • Single column format Dislikes • Single column format – harder to see information
Content	Dislikes: • Instructions – no specific dosing interval • Active ingredient – does not specifically state what it is • Missing information – duration of use • Unsure of whether to take with or without food as information has not been included	Likes: • Instructions – good that states times of day – clearer; clear that you need to spread out doses. • Expiry date – clear Dislikes: • Food – does not say whether to take with / without • Instructions – label states times of day rather than intervals – would prefer dosing intervals – people have different routines / work shifts • Queries: Alcohol use? Mix with other tablets? Use machines?	Likes: • Instructions – exact times specified; helpful; easier for people who struggle to spread doses • Information clear and easy to understand Dislikes: • A lot of information – all the times – but if necessary then it works	Likes: • Maximum dose clear Dislikes: • Missing information: - Whether can take in advance of pain - Do you take as soon as you get pain or do you wait? - Side effects - Can be taken with other medicines? - To take with / without food • Active ingredient – not clear which one • Instructions too lengthy across the label

Wording	Dose & frequency – mixed opinions re use of numbers or words Likes: • Instructions – simple • Straight forward, not confusing. • Frequency – four times a day – can be divided and measured Dislikes: • Dose & frequency – should not be a mix of words and numbers	Likes: • Instructions – easy to understand, straightforward • Dose – number 2 preferred to word two Dislikes: • Instructions – too many words – can start to overthink	Likes: • Instructions – clear regarding when to take it Dislikes: • Very specific – query about people who work night shifts – time intervals might be better	• Instructions - clear in general – but "when needed" a little confusing – comma before when needed is confusing • Dose, frequency, max number of tablets – mixed opinions regarding preference for numbers as words in upper case or numerals
Suspension				
	Label 9 (Cluster 1)	**Label 6 (Cluster 2)**	**Label 7 (Cluster 3)**	**Label 10 (Cluster 4)**
Design	Likes: • Bolding – key parts of directions bolded • Single column overall format – good • Line clearly separates the information Dislikes: • Dosage form – confusing; box confused this • Too much information on label • Design – everything in a small space, suboptimal spacing • Italics – unsure of its significance for vipparoll • Lower case vipparoll, that is, dislikes that it is not sentence case • Bolding distracting – makes eyes dart everywhere • Label size – small; might not be good for someone with poor eyesight • Hardest to follow of the labels but can still find all pretty easily • Expiry date located too close to the date of dispensing	Likes: • Bolding – important information bolded • Bolding – bolding of dose and frequency (best bolding of the labels tested), relevant parts of directions • Bold and upper case – for active ingredient - easy to find "brand" • Single column – horizontal line divider • Gaps – white spacing between top and bottom half made it clearer to process information • Readability – clear • Layout – perhaps as bigger and more spaced; familiar layout • Instructions – sentence format clear	Likes: • Bullets – better than sentence • Bullets – easy to find information / facts; gives dosage for each time of day • Bolding – in instructions; bolding of 9.5mL; "medicine name" / brand / title • Italics – good for 'active ingredient' • Medicine-related information clearer in single column format Dislikes: • Bullets – not as good as table but better than sentence	Likes: • Layout – clean; looks like a book • Easiest one to read / understand – on a bigger box; larger label • Bolding – good for emphasis of needed information (for example morning and night) • Bullet points – straight to the point, brief, emphasise instruction • Columns – easier to read • Size – prefer bigger label Dislikes: • Columns harder to follow • Label size slightly too big • Label is messy – no space between ingredients and how to take

Content	Likes: • Instructions – wait 6 hours instruction is good • Instructions – likes specificity of dosing intervals and max doses- can set alarm Dislikes: • A lot of content but not too bad • Standard information – a lot of unnecessary content • Too many numbers	Likes: • Food – states whether to take with food • Instructions – 'three times a day' generally fine/clear • Easiest to understand – least amount of information Dislikes: • Brand / Active – not as clear • Upper case – frequency 'three' not in upper case – not as clear • Unsure what 500mg/5mL suspension is • Query – child's age affect dose?	Likes: • Food – good that states whether to take with food Dislikes: • Instructions – Morning, afternoon and night vaguer than capsule label evaluated but still works • Instructions – does not state a specific time in morning • Missing information: dosing interval • Food – with food – confusing instruction • Instructions – child would go to bed early so is it night or evening?	Likes: • Patient name, expiry, doctor clear • Clear how much to measure and what empty stomach means • Tells exactly what empty stomach is; likes this detail • Information is the clearest Dislikes: • Query – Other side effects; missed dose • Missing content – dosing interval • Does not say dosage, just to take it morning and night (participant confusion)
Wording	Dislikes: • Medicine strength – confusing; confusion regarding dosage form • Instructions – a lot more words • Instructions – people may get confused as it does not say that one dose is 10mL	Likes: • "Seems fairly idiot proof" • Instructions clear Dislikes: • Likes sentence layout of instructions the least • Three times a day – people could misunderstand and could take three at once • With food – ambiguous – a little confusing as to what it meant	Likes: • Instructions – clear what to do Dislikes: • Dosage form – did not know what suspension meant	Likes: • Simple directions for use Dislikes: • Unsure of what 500mg/5mL was – confusing • Too many words, particularly in directions for use
Cream				
	Label 2 (Cluster 2)		**Label 5 (Cluster 4)**	
Design	Likes: • Bullets – good; easier to read/understand/remember; draws attention • Bolding – Likes bolding of 1 fingertip amount – specific instruction Dislikes: • Busy label • Columns – not as clear for processing information with columns • Does not like as much as tablets label as sentence then list and does not say how much to apply in each bullet point		Likes: • Columns – easier to read; tend to read left to right • Italic font used for brand name grabbed attention more than bolded word • Most important information on the left Dislikes: • Bolding – Query as to why "apply" was bolded; Bolding of apply – too generic • Information does not jump out as much – have to read • Patient name not as clear – a bit lost	

Content	Dislikes: • Too much information – Times of day superfluous / not relevant; would have preferred just 4 times a day; why is the label giving so much information • Missing information – dosing interval although specified 4 times / day use • Everyone has different daily routine so it does not make sense to participant • Query regarding what a fingertip amount is	Dislikes: • Dosage – missing information re how thickly to apply; amount of cream important • Content – No information: just cream, affected skin, morning and night • Missing content – how much to apply; side effects like photosensitivity, reactions on skin; treatment duration; indication; stain clothes?
Wording	Likes: • Easier one to understand • Fingertip amount is good; clear Dislikes: • Did not understand what fingertip actually means	Dislikes: • Unsure if should put cream a little around the area or just on it
Eye drops		
	Label 11 (Cluster 1)	**Label 12 (Cluster 3)**
Design	Likes: • Formatting of active ingredient and brand name clear • Columns – simple, nicely spread out; more straight forward with clerical bit on one side; easiest; likes split of information • Prefer upper case; more attractive and would want for the brand name • Bolding – "Perfect" use of bolding; bolding in instructions nice to read; 2 drops in bold • Bullets – may be easier for non-English speakers to process information • Indentation – more simple than huge chunk of sentence regarding instructions Dislikes: • Columns – more confusing • Formatting – Brand name and active ingredient do not need to be in upper case – not relevant to taking of medicine • Formatting – Confusing that brand name and active ingredient all in upper case – not distinct enough between the two • Inappropriately positioned 10mL • Indentation – Did not like the layout where information regarding each night was on a different line	Likes: • Easier label – maybe due to reading from left to right with the columns; two column format easy to understand • Bolding – in directions for use good; emphasises important information; fine – get what you need to do • Spacing – between information • Columns – Quantity stands out more so when reading down in column; "standard" information content clearer in two column format Dislikes: • 10 mL on one side and active on another – do not know if 10 mL of active ingredient or if net volume • Two column format not liked as much as single column; more confusing; line dividing two columns makes it confusing • Spacing – Extra information more cramped • Lack of bolding – Medicine name not bold therefore harder to read • More space with this layout – information on the right less important

Content	Likes: • D28 information – additional information to other labels • Level of content compared to other labels Dislikes: • Potential for confusion regarding the discard by instructions and expiry date • Missing content – treatment duration • Query – confusion regarding how many times the eye drops can be used • Could not understand medical name; confusion regarding which was the active ingredient • The amount of active ingredient was confusing	Dislikes: • Not clear – people will misunderstand brand name and active ingredient
Wording	Likes: • "Put" rather than "instil" • Simple wording like "put" and "throw" Dislikes: • Was not completely sure of what 1% was at first • Comma next to each night impaired understanding initially	Likes: • Directions straight forward, clear and stand out – easy to know dose Dislikes: • Word "two" would stand out better and bolded • Unsure if "1%" referred to 1% of active ingredient in the whole thing

Table 20. Suggested improvements for labels evaluated in Round 1 user testing (excluding "standard" information content feedback)

	Label 1 (Cluster 1)	Label 3 (Cluster 2)	Label 4 (Cluster 3)	Label 8 (Cluster 4)
Tablets/ capsules **Improvements needed**	Content • Addition – Instructions – some people wanted more specific dosing intervals • Deletion – medicine strength – perceived as unnecessary Bolding • Bolding – bold dose and frequency • Bolding – bold vipparoll • Instructions – put dose frequency in upper case as very clear; upper case and bold would be good • Upper case – myclofenac, vipparoll Order of active ingredient / brand name • Brand first; active ingredient second / under; or specify which is the active ingredient explicitly; or include active ingredient in brackets after the brand name • Move 100 caps for example higher up or include as part of the "title" Formatting of active ingredient • Centre brand name rather than include together with the active ingredient	Content • Addition – State warnings / side effects. • Addition – Instructions – should explicitly state dosing interval for example every 4 hours • Addition – Food – state whether with / without Bullet points • Instructions – list could be in dot points Formatting of active ingredient / brand name • Brand name – upper case name if both brand name and active ingredient are to be bolded Wording • Instructions – simplify – less words	Content • Addition – Instructions – include whether can take with food • Deletion – Instructions – would prefer without times of day if they are not necessary • Change – Instructions – changing to dosing intervals instead of set times might be better Bullet points • Could try changing to bullets Order of active ingredient / brand name • Brand first; active ingredient second / under Formatting of active ingredient / brand name • Brand – put in bold and capitals Colour • Put myclofenac written in red; information in blue	Content • Addition: Active ingredient – specify which word it is Bolding / emphasis • Bold / highlight / underline – maximum daily dose • Bolding – 6 hours, 8 tablets Formatting of active ingredient / brand name (and order) • Brand – put first in capitals, then active ingredient after Formatting – directions for use • When needed should be in another area with * or in brackets • Instructions – specify dose number, frequency and maximum number of tablets content in capitals instead of number, and maybe in bold as well Font size • Font – make bigger – so easier to read Wording • Alternative wordings suggested: - "Only for knee pain" - "Only 8 tablets each day"

	Label 9 (Cluster 1)	Label 6 (Cluster 2)	Label 7 (Cluster 3)	Label 10 (Cluster 4)
Suspension **Improvements needed**	Content • Addition – Instructions – specify that 1 dose is 10 mL • Addition – duration of use Wording • Instructions – make more simple / concise • SIX rather than 6 would be clearer Re-ordering label content • Include medicine name, then doctor and patient details and then directions for use; expiry date included near doctor name; reference number and pharmacy name at the bottom of the label; keep out of reach of children also at the bottom Formatting – directions for use • Bold – 10 mL and 6 hours, and 4 doses in 24 hours • Underline / italicise – "when needed for pain" • Bolding – only critical information, that is, "4 doses in 24 hours" Formatting of active ingredient / brand name • Vipparoll – v should be in upper case • Brand / Active – upper case myclofenac and vipparoll • Italics – avoid for 'vipparoll' • Bolding unnecessary for brand and active ingredient Colour / pictograph • Add colour / an image Label size Bigger label would have been better	Formatting of active ingredient / brand name • Prefer upper case for brand and active ingredient in lower case • Bold – brand name (and include strength next to active ingredient) Formatting – directions for use: • Bold (or underline) – with food to make clearer • Bolding – remove from 'measure' and 'child' Label size • Label size – decrease (but keep larger than smaller label)	Content • Addition – Instructions – should explicitly state give it three times a day • Addition – Instructions – would prefer times / time-frames to be stated • Addition – Instructions – need to be clearer as when exactly to take it with food Formatting of active ingredient / brand name • Brand – put first in bold and upper case Formatting – directions of use • Bold – morning, afternoon and night too (and include in upper case) • Highlight / underline / bold with food Font size • Font – include different parts in different font sizes – name of medicine should be bigger, instructions and other information slightly smaller	Content • Deletion – Non-important information • Addition – Treatment duration • Addition – Further explanation • Addition – Include other ingredients in case of allergy Wording • Can shorten some parts for example should have just said 5 mL morning and night Order of active ingredient / brand name • Mixicillin should be on top (brand name- upper case suggested) and then active ingredient under (lower case suggested) – brands easier for people to understand Formatting – directions for use • Bold empty stomach • Could have used brackets after empty stomach and said (30 minutes before food / 2 hours after) instead Label size • Could make label bigger

	Label 2 (Cluster 2)	Label 5 (Cluster 4)
Cream **Improvements needed**	Content • Addition – More specific direction as to what a fingertip amount is (however would be fine if pharmacist explained) • Deletion – Just state four times a day Pictograph • Maybe include graphic to show where to measure cream Formatting of active ingredient / brand name • Bolding product name would help to make it easier to find Location of information on label • Name should be first to read – in same column as directions	Content • Addition – Should state how much to apply • Addition – Should state indication • Addition – Treatment duration • Addition – Should state whether to rub it in or just leave it on top then wipe away • Addition – Would like to know other ingredients / composition of cream Formatting – directions for use • Bold morning and night instead as important information • Bold affected skin Pictograph • Maybe could use a graphic to show the quantity to apply • Could include bullet points as there is available space – could say how much to use
	Label 11 (Cluster 1)	**Label 12 (Cluster 3)**
Eye drops **Improvements needed**	Position of information • 10 mL should be closer to brand Bolding • Bold expiry date • Bold “left eye” – important • Bold “throw away” instructions • Bold “each night” to help easily identify that it is only to be used at night Formatting – directions for use • Bullet points could have worked • State throw away directions in upper case – important • Prefer directions for use statement on the one line (not as indented list) • ml not mL Order of active ingredient / brand name • State Lubidrops (brand name) first / at top (leaving in bold and upper case) • Active ingredient below brand or in brackets Formatting of active ingredient / brand name • Have hypromethylmellose in italics but not bolded – not as important • Reserve upper case for brand name; ingredient should not be in upper case or bold as not main focus Pictograph / colour • Eyeball with water • More colour added to label Label size • Make label cover whole side of box	Content • Should state how many mLs of active ingredient is in Formatting of active ingredient / brand name • Prefer medication name in bold Order of active ingredient / brand name • Lubidrops (brand name) at top then active ingredient under Formatting – directions for use • Night in all capitals • TWO / Two bolded instead of 2 would be better Bolding • Bold throw away instruction Column division • Make division line between columns thicker Colour • Have different colours for both halves of the label Other • Include date opened… (with space to write date) so can remember when opened

Perspectives on the various "standard" information content formatting

Participants raised several comments relating to the "standard" information content on the label and how it was formatted (Table 21). They also suggested improvements to the "standard" information content (Table 22). A number of comments were made about the labels which were actioned for Round 2 label development. These included placing the patient name under the doctor name; clearer and logical presentation of information for reading from left to right; ensuring that expiry date stood out; specifying "quantity"; and ensuring that "keep out of reach of children" was in a smaller font but still stood out.

Table 21. Participant perspectives on the "standard" information content[a] and content formatting included on each study label in Round 1

Format	Labels	Design	Content
Single column	1, 6, 7	Comments • Co-location of the date of dispensing and the expiry date can cause confusion (N.B. mentioned across multiple label formats) • Expiry date – seemed hidden (Label 6), took more effort to locate (Label 1) • Clear; however, another participant said the format of two columns within the bottom row was not good (Label 6) • Unnecessary content that appears to be cramped (Label 1)	Participants did not know what the reference number meant → not perceived to be something important to know
	4, 8, 9	Comments • Liked patient name written directly below doctor name (Label 9) → Retained to an extent for at least one Round 2 label Dislikes: • Standard information layout difficult to read (Label 9) • Patient name – not as clear; too small (Label 9) • Expiry date – a bit small (Label 8); too close to dispensing date – confusing (Labels 8 and 9) • Unsure about layout / order of information; read from left to right therefore name, 100 caps, and expiry date does not make sense (Label 4) → Actioned for at least one Round 2 label (changes made accordingly)	

Two column	2, 3, 5, 10, 11, 12	Comments
		• Information separated out with the two column format
		• Mixed opinions regarding clarity of the two column format – some felt it was confusing, others thought it was clear:
		  ○ Two column format clearer – can just look at the left hand side with the directions for use; would only look at the other side for expiry date (Label 10); liked "standard" information content on right and was in the general order of necessity (Label 12)
		  ○ Two column format not liked as much as single column (Label 2); did not like two column format (Label 11)
		• Patient name clearer – more space between quantity and name (Label 10)
		• Placement of expiry date next to the dispensing date is confusing (Label 11)	

[a] "Standard" information content refers to all other information included on the label (except the active ingredient, brand name, and directions for use).

Table 22. Suggested improvements by participants for the "standard" information content on the labels

Format	Labels	Design
Single column	1, 6, 7	Suggested improvements (specific label referred to for improvement) • Font – increase font size of medicine-specific content in comparison to "standard" information content (Label 6) → Actioned for at least one Round 2 label • Move patient name above the line to make it clearer (Label 6) → Actioned for at least one Round 2 label • Include doctor name under patient name, similar to Label 11 (Label 1) • Have quantity and expiry in larger font than date, doctor name, and pharmacy address so it stands out (Label 6) → Actioned for at least one Round 2 label • Put "keep out of reach of children" below the pharmacy address (Label 6) → Actioned for at least one Round 2 label • Include "keep out of reach of children" more clearly on label (Label 1) • Pack quantity – state in the top half of label or as part of the label title (Label 1)→ Actioned for at least one Round 2 label • Include dispense date in the top half of the label (Label 1) (top right corner) • Make expiry date stand out a bit more (Label 1) Other comments • Label 1: "Standard" information – should be on a different side, except for expiry date → Not taken forward to Round 2
	4, 8, 9	Suggested improvements (specific label referred to for improvement) • Number of caps to be included at the top with the product name (Label 4) → Actioned for at least one Round 2 label • Expiry – split expiry date and dispensing date by stating the reference number in between; clearly separate the two (or bold / underline) (Label 8) → Actioned for at least one Round 2 label • Make expiry date stand out a bit more / bold expiry date (Label 9) → Actioned for at least one Round 2 label • Bold and move expiry date to the bottom of the label (Label 9) to make it more easily visible (or put at top) • Make "keep out of reach of children" smaller than other content (Label 8) → Actioned for at least one Round 2 label • Move reference number to the bottom – not important (Label 9) → Actioned for at least one Round 2 label • Move pharmacy address, doctor name, reference number, dispensing date to another side of the box (Label 9) → Not taken forward to Round 2
Two column	2, 3, 5, 10, 11, 12	Suggested improvements (specific label referred to for improvement) • Most important column should be wider than the column containing "standard" information content (Labels 2, 5, 10) → Actioned for at least one Round 2 label • Place "keep out of reach of children" at the top, maybe like the Fred label (Label 10) → Actioned for at least one Round 2 label • Pharmacy address in smaller font size (Label 10) → Actioned for at least one Round 2 label • Bold expiry date so that it is not confused with the dispensing date (Label 10) → Actioned for at least one Round 2 label • Include expiry date directly below the directions for use (Label 11) → Actioned for at least one Round 2 label • Specify "quantity" and then state quantity, that is, quantity 100 mL (Label 10) → Actioned for at least one Round 2 label • Prefer doctor name under patient name, similar to the suspension label (Label 11) → Actioned for at least one Round 2 label • Move reference number to the bottom of the label (Label 12) → Actioned for at least one Round 2 label

3.2 Round 2

3.2.1 Participant demographics

Overall, there were approximately equal numbers of male and female participants across both clusters (Table 23). The majority of participants were aged between 18 and 49 years, and spoke English as their main language at home.

Table 23. Summary of participant demographics – Round 2 user testing

Demographic		Cluster 5 (n=10)	Cluster 6 (n=10)	Total (n=20)
Gender	Male	5	4	9
	Female	5	6	11
Age (years)	18-29	4	4	8
	30-49	3	5	8
	50-69	3	1	4
Highest level of education attained	School certificate (Year 10) or below	0	1	1
	Higher School Certificate (Year 12) or college qualification	6	4	10
	Bachelor's degree or higher	4	5	9
Regular use of written information as part of occupation	Yes	8	6	14
	No	2	4	6
Main language spoken at home	English	6	7	13
	Other	4	3	7
Country of birth	Australia	7	5	12
	Other	3	5	8

With respect to self-reported understanding of health and/or medicine-related information, 17/20 participants were extremely or quite confident in completing medical forms independently (Table 24). The same proportion reported never having difficulties learning about their medicines and/or conditions due to difficulty in understanding written information or only having difficulties a little of the time (Table 24).

Table 24. Round 2 participants' self-reported understanding of health and/or medicine-related information (n=20)

Question		Participant responses Number of participants				
		1	2	3	4	5
1. How confident are you filling out medical forms by yourself?[a]	Cluster 5	0	0	2	5	3
	Cluster 6	1	0	0	5	4
2. How often do you have someone help you read written medicine information?[b]	Cluster 5	7	2	1	0	0
	Cluster 6	7	3	0	0	0
3. How often do you have problems learning about your medical condition or medicines because of difficulty reading and understanding written information?[b]	Cluster 5	7	1	1	1	0
	Cluster 6	4	5	1	0	0

[a] The scale of 1 to 5 denotes: 1=not at all, 2=a little, 3=somewhat, 4=quite, 5=extremely.

[b] The scale of 1 to 5 denotes: 1=none of the time, 2=a little of the time, 3=some of the time, 4=most of the time, 5=all of the time.

3.2.2 Label reading times

Overall, the average reading time per label ranged between 14.4 seconds (Label 14A) and 29.8 seconds (Label 15).

3.2.3 Round 2 user testing – quantitative findings

Overall, all Round 2 labels performed well when evaluated within each cluster (Table 25).

Table 25. Summary of Round 2 user testing findings (quantitative)[a]

	Tablet / capsule labels						Suspension labels				Cream label		Eye drops label	
Label cluster	5 and 6		5		6		6		5		5		6	
Label	Label 13		Label 14A		Label 14B[b]		Label 15		Label 16		Label 17		Label 18	
Found (n) Understood (n)	F[c]	U[c]	F	U	F	U	F	U	F	U	F	U	F	U
	(n=20)		(n=10)		(n=10)		(n=10)		(n=10)		(n=10)		(n=10)	
User testing questionnaire (UTQ) item														
Name of patient					10	10					10	10		
Active ingredient			7	7	1	1	10	10	10	10	8	8	9	8
Strength			9	9	10	10	9	9	10	10	9	9	6	6
Expiry date					10	9					10	10		
Dosage	20	20	10	10	10	10	10	9	10	10	10	10	10	10
Testing of dosing table[d] (appropriate dosing schedule)			5		7									
Use in relation to food							10	10	10	10				
Maximum dose *(prn medicine)*	20	20												
Discard-by date													10	10

[a] Each participant evaluated three different labels in one of the following orders: 1) A cream label (Cluster 5) OR capsule label (Cluster 6); 2) A suspension label (both Clusters 5 and 6) and; 3) A capsule label (Cluster 5) OR eye drops label (Cluster 6). Every participant reviewed Label 13 as the last label to be user tested in each cluster for Round 2 – only the dosage-related questions were asked.

[b] Label 14B is the 7th label requested by Canberra Hospital for inclusion in Round 2 of the user testing.

[c] F = Found (number who found the relevant information on the label); U = Understood (number who understood the relevant information found).

[d] This question involved a show card which was provided to the participant. For this question, the participant was required to plan a daily dosing schedule for 3 hypothetical medicines they were currently taking, plus the new medicine corresponding to the label that was being tested. As dosage was addressed in a previous question, responses were coded using the dosing schedule. Therefore, the number of participants denotes the number who were able to plan an appropriate dosing schedule.

Tablet / Capsule labels

For the capsule labels (Label 14A and 14B) and the tablet label (Label 13), all participants were able to find and demonstrate appropriate understanding of the dosage. Furthermore, all participants could find and understand the relevant information pertaining to maximum dose for the tablets (Table 25).

Based on the coding framework applied to evaluate participants' ability to plan a daily dosing schedule for the fictitious medicine (myclofenac capsules) and the other three concurrent medicines (medicines X, Y and Z), 8/20 participants planned inappropriate schedules. The reasons identified were:

- Overall difficulty in completing the table (n=1);
- Short dosing intervals –
    - Medicine X and myclofenac (Brand name: Vipparoll) (n=1);
    - Medicine Z, taken twice a day, specified to be taken too close together (n=1)
- Incorrect dosing times –
    - Medicine X, taken three times a day, was reported in the dosing schedule to be taken as morning, evening, and bedtime (n=1);
- Vipparoll dosing issues –
    - gap between evening and bedtime dose specified as less than 6 hours (n=3; Label 14A))
    - dose missing (n=1) (and Medicine X dosed morning, evening, and bedtime)

Similar to Label 17, almost all participants evaluating Label 14B were able to find and understand the patient name and expiry date. However, for the one participant who could not understand the expiry information, they stated that the "9" in "9/2021" could represent the date or the month ("it could be the 9th month or it could be the 9th day").

The participant who could not locate the medicine strength for Label 14A stated that the information is not on the label and the participant thought that the active ingredient was "a percentage of that 75 mg".

Suspension labels

Overall, the suspension labels performed well. One participant who evaluated Label 15 struggled with the strength and dosage of the suspension; the participant was confused between strength (expressed as per 5 mL) and dosage (9.5 mL dose).

Cream label

All participants could find and understand the name of the patient, expiry date, and dosage on the cream label. Two participants were unable to correctly determine the active ingredient. One participant could not find the strength of the cream (0.5%) on the label and stated 50 g as the strength, demonstrating confusion between strength and the quantity of cream.

Eye drops label

Dosage and expiry date were found and understood by all participants who evaluated the label. Active ingredient was not able to be determined by one participant. Another participant correctly stated that they thought the active ingredient was hypromethylmellose initially, but then stated that they were not sure. Therefore, this response was coded as found and not understood.

The notable finding for the eye drops label was that 4/10 participants were unable to find the strength of the eye drops. Participants stated that the eye drops contained 10 mL of active ingredient, demonstrating confusion between quantity of the eye drops and the strength.

3.2.4 Active ingredient versus brand name formatting

Overall, when examining all Round 2 labels and the subsequent formatting of the active ingredient and brand name information, there may be several interpretations that can be attributed to the quantitative findings for each label (Table 26). There are some noteworthy findings:

- Sign-posting of the active ingredient and brand name led to more participants being able to identify the active ingredient and brand name
- Participants are accustomed to having the brand name first followed by the active ingredient. Changing this order led to difficulty in identifying the active ingredient

Table 26. Summary of Round 2 user testing findings for the active ingredient UTQ items

Dosage form	Label	Cluster	Active ingredient (AI) and brand name (BN) formatting and position	No. found and understood active ingredient[a]	Comments
Tablets / capsules	13	5 and 6	BN, Sentence[b] **Bold**, above AI, Sentence, below	- (not asked)	• Prior to evaluating Label 13, all participants user-tested either Label 14A or Label 14B (which had the same medicine names). The focus of evaluation for Label 13 was on dosage-related information only
	14A	5	AI, Sentence **Bold**, above BN, Sentence, below	7	• Compared to 14B, Label 14A was evaluated as the third label in Cluster 5, after the suspension label which had sign-posting of the active ingredient and brand name. Therefore, this may explain why there is such a marked difference between the performance of these two labels and highlights the benefits of sign-posting for medicines where the brand name and active ingredient do not markedly differ in their jargon-like nature
	14B	6	AI, Sentence **Bold**, first BN, Sentence, in brackets next to AI	1	• Tested as first label in Cluster 6; myclofenac and vipparoll are not distinctive in terms of which "sounds" like an active ingredient. It is likely that people still routinely associate the brand name as the first thing presented on a label (current practice with dispensing software(s) and subsequent prescription medicine labels produced). This may explain why such a low number got this correct. Also, as per Round 1 feedback, bolded text signified brand name for some participants therefore the fact that active ingredient was bolded, together with being stated first, has likely compounded this misunderstanding
Suspension	15	6	BN, Sentence **Bold**, above AI, Sentence **Bold**, below Sign-posted BN and AI	10	• Tested as second label in Cluster 6; explicitly stated which was the brand name and which was the active ingredient (sign-posting), hence all participants could find and understand the information
	16	5	AI, Sentence **Bold**, above BN, UPPER CASE **Bold**, below Sign-posted AI and BN	10	• Tested as second label in Cluster 5; explicitly stated which was the brand name and which was the active ingredient (sign-posting), hence all participants could find and understand the information
Cream	17	5	BN, Sentence, above AI, lower case, below in brackets	8	• Tested as first label in Cluster 5; brand name was presented first on this label, with active ingredient in brackets – this is likely why a large proportion could identify the active ingredient as this is routine practice for current labels (for example Fred dispensing software label) • Another key change was that the brand name for this label in Round 2 was not italicised; Round 1 label had the brand name italicised which led to misunderstanding that it was the active ingredient
Eye drops	18	6	AI, Sentence, above BN, Sentence, below	8	• Tested as third label in Cluster 6

[a] < 5 found and understood = cell highlighted in red; > 5 found and understood = cell highlighted in green.

[b] Refers to Sentence case.

3.2.5 Applied understanding of dosage instructions

Pain scenario and dosing with reference to the capsule labels

Participants were asked how they would take myclofenac if their pain started at 9 am that day when user testing Label 14A or 14B. Both labels had a dosage table to increase understanding of dosing. However, Label 14A had a dosage of 1 capsule four times a day with a 6-hour dosing interval explicitly stated, and Label 14B had a dosage of two capsules twice a day.

Overall, Label 14B appeared to better support participants' ability to apply their understanding of how to appropriately dose the fictitious medicine in relation to the given scenario (Table 27). Only half of those participants who read Label 14A were able to appropriately dose the medicine.

Table 27. Coding of responses to the probe question regarding dosage and pain scenario for capsule labels from Round 2 (n=10 per label)

Label	Appropriate dosing intervals	Inappropriate dosing interval(s)			
		Shorter dosing interval(s)	Longer dosing interval(s)	Shorter and longer dosing intervals	Dose omitted
14A	5	2	0	0	3
14B	10	0	0	0	0

Label 14B conveyed a simpler dosage regimen of two doses for the day (2 capsules in the morning and at bedtime), and all participants were able to appropriately nominate when they would take it as per the table on the label itself.

In comparison to the responses received from participants in Round 1 regarding Label 1, which also included directions of taking "1 capsule four times a day", 3/10 respondents who reviewed Label 14A opted to omit a dose, that is, take only three doses for that day in response to the pain scenario. This highlighted that attempted observance of the 6-hour dosing interval took precedence over the direction to take four doses per day for these participants.

> *"Like, 3am – yeah calculating by this. But I think it's not practical like, yeah…… If it's for me I might just wait… wait till I wake up, to have the next one." (P42)*

> *"I'd only take it twice if it's every 6 hours…… Oh actually, would I take 1 [capsule] at 9[am] when it first starts? Hey, I guess I would take it at 9. I'm just thinking to myself. So I'd take it 3 times that day." (P50)*

> *"I'm assuming I'd be asleep for the next dosage [last dose of the day]." (P57)*

Two participants in Round 2 did not consistently observe the 6-hour dosing interval as per the instructions on the label. One participant shortened the interval between the previous dose and final "bedtime" dose for the day *"because I went to bed, you know, midnight" (P43).* The second participant adjusted all intervals to less than 6 hours across the day (waking day).

Amount of cream to be applied

Overall, the responses received by participants in Round 1 in relation to this probe on the amount of cream to be applied were similar to those observed in Round 2.

Similar to previous comment(s), one participant mentioned that the amount of cream was deemed to be dependent on the size of the area of affected skin. Another participant thought that the fingertip direction related to the area of skin that the cream should be applied to, rather than the amount of cream itself.

> *"I'm thinking maybe the affected area is a small area, and you want to cover the area with like a fingertip worth in like circumference in the area. So not like a fingertip worth of cream, but more so like the amount of area that you like rub it into is about a fingertip. So, like 2 cm." (P58)*

Again, a question was also raised as to what constituted a fingertip: *"that's not a fingertip is it, that's like a third of a finger…" (P50)*. Where a few participants would squeeze an amount to cover the end of the finger (that is, down to the first crease of the finger), others would either go only halfway down to the first crease or just the top / end of the finger itself.

3.2.6 Performance of Round 2 user testing labels with respect to industry standards

Overall, a larger proportion of labels met industry user testing standards in Round 2 compared with Round 1 (Table 28). Importantly, active ingredient identification for Labels 15 and 16 performed well in Round 2. There was a worsening of medicine strength identification for Label 18, due to a change in the positioning of the bottle quantity.

Table 28. Comparison of Round 2 user testing findings to industry testing standards

Dosage form	Label	Met industry requirements for <u>all</u> UTQ items[a]	UTQ item(s) responsible for not meeting minimum requirements
Tablets / Capsules	13	✓	
	14A	✓	
	14B	✓	
Suspension	15	✓[b]	
	16	✓[b]	
Cream	17	✓	
Eye drops	18	✗	Medicine strength

[a] UTQ data for active ingredient identification and dosing schedule tabulation have been excluded. None of the labels met the industry standard for participants finding and understanding the active ingredient, except for Labels 15 and 16.

[b] Labels 15 and 16 explicitly stated which was the active ingredient and which was the brand name (sign-posting). They demonstrated superior performance regarding active ingredient identification over all other labels.

3.2.7 Semi-structured interview findings: label feedback and perceived improvements required

Due to the changes made to the formatting of the active ingredient and brand name in Round 2, specific feedback was sought from the participants on these formats.

Active ingredient versus brand name identification

In comparison to Round 1, similar self-reported factors were reported by participants that impacted how they differentiated between the active ingredient and brand name. Participants believed that:

- Active ingredient would be below the brand name on the label
- Active ingredient would be in brackets
- Active ingredient would be next to medicine strength, for example in Label 14A myclofenac was next to 75 mg (medicine strength) and therefore was reported to be the active ingredient
- Brand name would be bolded, for example myclofenac bolded on Label 14A therefore participant thought that it had to be the brand name
- Active ingredient was in medical jargon

An interesting remark regarding brackets was that brackets *"makes it seem like it's just a shorter way of saying something fancy"* (P45) (in regard to Tapisoy, and therefore why Tapisoy was incorrectly reported as the active ingredient).

Overall, participants liked the sign-posting of the active ingredient and brand name, which was unique to Round 2 suspension labels (Table 29).

Participant perspectives on the design, content, and wording used on the labels evaluated in Round 2 user testing

The feedback provided by the participants were categorised into "likes" and "dislikes" under the broad themes of design, content and wording of the labels, as well as the participants' suggestions for improvements (Table 29). Round 2 participants were receptive towards the tabulated dosing schedule included in Label 14A and 14B, particularly in Label 14B.

Table 29. Participant perspectives on the design, content, wording, and suggested improvements for the labels evaluated in Round 2 user testing (excluding "standard" information content feedback)

	Tablets / Capsules		
	Label 13 (Clusters 5 and 6)	**Label 14A (Cluster 5)**	**Label 14B (Cluster 6)**
Design	Likes: • Selective bolding for emphasis • Position of directions for use in the centre of the label Dislikes: • Expiry date in the wrong place • Key information such as only take in knee pain, was read last • Small font harder to read • Quantity difficult to find	Likes: • Table – forces label to have more structure, helps to separate out information on the label; reinforces when to take the medicine at a glance within the table, simple to understand • Bolding for emphasis: dosage • Bolding of the "brand" • Position of quantity Dislikes: • Did not like table for instructions – 6-hour intervals did not match with morning, midday, evening and bedtime • Table wastes space, was not helpful • Aesthetically, did not like stating "1 capsule" repeatedly on the label	Likes: • Table – easy to follow, clearer, reinforces when to take the medicine at a glance within the table • Blacked-out squares – on dosing table – emphasises not to take at those times • Bolding – "myclofenac" • Clear spacing of information Dislikes: • Blacked-out squares – Confusion regarding blacked-out squares initially; thought could take at those times but then realised was not meant to
Content	Dislikes: • Missing key headings • Active ingredient / brand name unclear • Too many words	Likes: • Dosing interval good as can tailor to day • Table and approximate times of day included in table were helpful • Inclusion of quantity; quantity clear Dislikes: • Time interval hard to abide by to fit into the proportion of the day spent awake; difficult to abide by 6-hour dosing interval • Table – still quite vague as the explicit time-frames are not included in the table, confused as to what exact time to take the dose • Table with approximate times found to be redundant • Most confusing of the labels • Difficult to clearly understand which is active ingredient / brand name (for example bolding caused confusion)	Likes: • Approximate times of day together with explicit time-frames – clear, helpful • Includes directions for use both as a statement and a table • Quantity clear Dislikes: • Difficult to clearly understand which is the active ingredient or brand name • Evening could range between 5 pm and 11 pm – ask the patient whether they would like the time there

Wording	Dislikes: • Not clear as to whether the medicine can be taken if less than 6 hours has lapsed (re the dosing interval)		
Improvements needed	Content • Should have some sort of heading that states "how to take the medicine" • If had set times, would be more specific • Take with / without food Active ingredient specification • Sign-post active ingredient / brand name (similar to suspension label) Information positioning • Expiry date should be at the top (just below active ingredient / brand name) • Quantity should be at the top in brackets Wording • Re-order the wording of the statement as the key thing is to only take it if you have knee pain as it is a prn medicine, that is, "when you have knee pain, take two tablets." • Be more specific in wording about whether the medicine can be taken if less than 6 hours has lapsed	Content • Deletion – 6-hour dosing interval (just said four times a day; replace with explicit times to take the medicine; not needed) • Addition – Explicit time-frames in the table • Replace "1 capsule" in the table with the actual times that the medicine is to be taken • Deletion – "1 capsule" in the table Active ingredient specification • Sign-post active ingredient Order of active ingredient / brand name • Active ingredient underneath brand name Format • Change to two column format	Content • Include capsules after the number "2" included in the table • Include indication • Include treatment duration , for example "until all finished" • Take with / without food • Include statement along the lines of "this box contains 100 mL of a medicine" Active ingredient specification • Sign-post active ingredient / brand name Bolding / emphasis • Not essential to have the "2" bolded Formatting – directions for use • Delete columns corresponding to midday and evening in table – redundant as no doses are taken at those times Other • Add a border to the label

	Suspension label	
	Label 16 (Cluster 5)	**Label 15 (Cluster 6)**
Design	Likes: • Bullet points – useful, easier to read • Clearly set out paragraphs • Bolding for emphasis – dosage • Layout Dislikes: • Information not clearly broken down with respect to design, as there was perceived to be four groups of information	Likes: • Font size easy to read • Selective bolding for emphasis– directions for use • Bolding of both active ingredient and brand name Dislikes: • Query as to why both active ingredient and brand name are bolded
Content	Likes: • Sign-posting of active ingredient / brand name is very clear • Information regarding empty stomach good Dislikes: • Too many different numbers confuse things – 500mg/5mL, then measure 5 mL, then 100 mL (bottle quantity) • Detailed instructions – can be confusing	Likes: • Sign-posting of active ingredient / brand name is very clear • Detailed • Clearest quantity of the labels (as stated quantity in brackets) • Dosing interval of 6-8 hours • "With food"
Wording	Likes: • Best wording of the labels evaluated • Directions clear Dislikes: • 500mg/5mL – unclear, confusing, difficult to understand; does not know what it means if do not have a science background • Instructions not that clear – does not stand out • "100 mL" confusing / unclear	Likes: • Medicine strength expressed as a sentence Dislikes: • Medicine strength – confusing
Improvements needed	Content • Deletion – medicine strength Information positioning • Move 100 mL to left hand side, underneath medicine strength/ingredient information, then include expiry date below • Move 100 mL to after syrup, and also stating "Quantity:" before it (preference for all medicine-related information to be on the left hand column) • Include keep out of reach of children statement below after directions for use • Expiry date should be in left hand column similar to cream label	Content • Explicit times to take (similar to Label 14B) Formatting of active ingredient / brand name • Remove bolding of active ingredient and brand name (as it does not provide further added benefit for emphasis as they are already sign-posted) Formatting – directions of use • Replace the bolded font with different coloured font instead • List out the individual components of the directions for use for simplicity (rather than have as continuous sentence), with appropriate headings

	Wording • Explain / more clearly express 500mg/5mL , for example “Each 5 mL of syrup contains…” Formatting – directions for use • Bold ‘empty stomach’ Formatting of active ingredient / brand name • Unbold active ingredient, and include as smaller font Formatting of label • Have three columns instead of two, to separate out patient information, medicine information, and information such as keep out of reach of children	Label format • Include directions at the top

	Cream	**Eye drops label**
	Label 17 (Cluster 5)	**Label 18 (Cluster 6)**
Design	Likes: • Position of expiry date (easily accessible) • Use of brackets to indicate the active ingredient	Likes: • Selective bolding (directions for use, discard-by directions) Dislikes: • Lack of bolding – active ingredient / brand name • Small font harder to read
Content	Likes: • Easy label	Likes: • Discard-by information Dislikes: • Active ingredient / brand name unclear
Wording	Likes: • Overall concise wording but details all information Dislikes: • Unclear / ambiguous / confusing wording regarding fingertip directions (down to first crease or just the very tip of finger?) • Instructions not that clear – does not stand out • Medicine strength unclear	Likes: • Four weeks is easier to manage than 28 days • "Throw…" Dislikes: • Medicine strength unclear
Improvements needed	Active ingredient specification • Clearly sign-post active ingredient and brand name, similar to expiry date and quantity Content and wording • Include more headings • Simplify wording of how much cream to apply • "pea-sized amount" or "dollop" type of expression to replace fingertip amount of cream description Bolding • Bold empty stomach • Bold Tapisoy (brand name)	Active ingredient specification • Sign-post active ingredient Content and wording • Prefer "Discard contents…" instead of "Throw the bottle away…" • Would be useful to specify what the date of dispensing is to assist with actioning the throw away contents date • State "this box contains 10 millilitres of the eye drops" Formatting of active ingredient / brand name • Brand presented using larger font Formatting – directions for use • Put left in upper case (LEFT) and include two as the number 2 instead – perhaps even underline "LEFT" Bolding • Unbold "each"

Perspectives on the various "standard" information content formatting

Various opinions were also raised in relation to the "standard" information content formatting in Round 2 (Table 30).

Table 30. Participant perspectives on the "standard" information content[a] and content formatting included on each study label in Round 2

Format	Labels	Design	Content
Single column	13, 15	• "Artificial column on the right" created with the reference number and pharmacy name – gap can lead to inadvertent skipping of the information (Label 13) • Small font for Keep out of reach of children statement – are more focussed on the medicine name (Label 13) • Close proximity of patient name and doctor name made it a little confusing initially (Label 13) • Preference for Label 15 label format – appealing design • Likes line that helps to space out the content (Label 15) • Logical order / arrangement of content (Label 15) – likes bolded expiry date <u>Suggested improvements</u> • Put line on Label 15 above patient name and expiry date – better partitioning point • Would include keep out of reach of children in red (Label 15) • Move expiry date nearer to maximum daily dose or the top of the label (Label 13)	Mixed opinions: Good to include reference number; Do not know what the reference number is; Could consider deleting reference number and dispensed date
Single column (with table)	14A, 14B	• Keep out of reach of children more noticeable at the bottom (Label 14A) – Preference over the position on other labels • Preference for "standard" information content layout for Label 14A (in a line) • Like patient name on top (Label 14B) <u>Suggested improvement(s)</u> • Did not like patient name at top, separate from all other "standard" information content (Label 14B) – would prefer for all this information to be grouped together; did not feel the need for it to be at the top	
Two column	16, 17, 18	• Preference for two column – clearly separates out personal information from medicine information (Label 16, 17) • Likes line that helps to space out the content (Label 18) • Column format can make one column appear more important than the other • Prefer two column format for cream label rather than suspension label as the expiry date was included in the left hand column (Label 16, 17) • Difficult to see pharmacy name (Label 17) • Hard to find expiry date as not in bold (Label 18) <u>Suggested improvement(s)</u> • Position of patient name does not make sense (Label 18) → suggest to move it to anywhere else as its present position still makes it as positioned in the "middle" of the information, following on from how columns are navigated from left to right • Bold patient name (Label 17)	

[a] "Standard" information content refers to all other information included on the label (except the active ingredient, brand name, and directions for use).

Pooled Round 1 and 2 participants' general perspectives on content and formatting considerations

Participants voiced mixed opinions overall on the various formatting and content considerations that were seen across Round 1 and 2 label formats (Table 31), as well as about the "standard" information content (Table 32).

Table 31. Round 1 and 2 participants' general perspectives on formatting and content

Formatting aspect	Comments
Active ingredient and brand name formatting	• General preference for brand name to be stated before active ingredient • Would prefer to have brand name bolded or in upper case or larger font, over active ingredient (active ingredient not held in high importance) • Use of brackets around active ingredient would be good
Specificity of dosing intervals / times on labels	• People generally liked specificity on labels • Would prefer both number of doses a day as well as explicit dosing interval to be included on the label • However, it was noted that specific times on a label do not account for the needs of the specific individual
Bolding	• Selective bolding for emphasis favoured • A few did not notice the bolding differences across the different labels for directions for use; not as imperative as they would read all information anyway
Numbers versus words for numerical dosage information	• Mixed opinions, however general preference somewhat for numerals • Happy to stick with current convention in practice regarding numbers and words (combination use) if people are used to it • Preference for words over numbers; but there would be no issue with reading numbers • Does not matter if words or numbers – all mean the same; no preference • Numbers better – stand out more, easier to understand than words, easier to identify (than words), are universal, concise • Would appreciate consistency in presentation of numbers using words or numerals • More elegant using words but more useful if using numbers

Table 32. Participant perspectives on broad "standard" information content formatting

"Standard" information content formatting aspect	Comments
Keep out of reach of children statement	• Mixed opinions • Good in red – stands out • Not as bothered re position on label • Preferred at the top of the label • Preferred in red and upper case at bottom; upper case can look sharp, austere • Keep out of reach of children in black font is not as easy to spot as when in red font • Make it bigger font
Expiry date	• Mixed opinions • Quite a few people liked this in bold so it stands out; perceived it as important • Few people did not mind if was not in bold – they did not class expiry as important as the people who preferred it to be bolded
Single column versus two column format	• Mixed opinions • Single column made the label easier to read rather than the two column format; as more used to the single column format • Two column made it appear like the information was being squeezed into a small area • Like because it separates medicine information from extra information • Did not like because makes you look at everything all at once (two column), competing for attention; did not like it as two column format is unfamiliar
Position of patient name	• Mixed opinions on position of patient name
Label size	• Mixed opinions • Larger label better, clearer; for older people, larger labels would be better • Need to balance content formatting versus content inclusion considering the label size • Package size constraints acknowledged with respect to label size, for example will have difficulty in fitting the table onto the smaller label • Okay with smaller label – compact and has all the information there • Likes smaller label size

4. Discussion and Conclusion

In this study, combining good information writing and design principles, the expertise of the research team and the application of user testing supported the development of dispensed prescription medicine labels that performed well, as observed when applying the industry standard criteria for user testing. Through iterative revisions and testing, Round 2 labels collectively performed better than Round 1 labels. When examining key label performance issues, active ingredient identification in particular proved to be the most problematic information item to identify by participants in both rounds of user testing. Factors influencing people's decision-making when trying to identify the active ingredient included:

- how technical the term was perceived
- the location of the active ingredient
- use of upper case, bolding, or italics
- co-location of medicine strength and active ingredient

Notably, sign-posting the active ingredient and the brand name led to all participants evaluating the label to correctly identify the active ingredient.

How the dosage information was expressed was found to influence how well participants could apply the information to a dosing scenario. In addition, other points of confusion for participants revealed during the user testing rounds included misunderstanding medicine strength and quantity (pack size). Participant opinions were mixed for the various label designs and formats, which reinforced that one label design was not superior over another; rather, positive labelling design aspects were identified that can be taken forward for inclusion in labelling guidelines and standards.

4.1 Active ingredient / brand name positioning and formatting

Active ingredient identification was the most common problematic item of information to be found and understood by the participants. This is a novel finding that has not been demonstrated by other researchers. Previous prescription label studies have largely focused on evaluating understanding of the dosage and direction for use on labels.[3, 11, 19-25]

This study revealed that a number of factors provide people with context when trying to identify and differentiate between the active ingredient and brand name. These factors included the formatting, positioning and nature of the medicine names. For instance, active ingredient prominence conveyed through formatting, such as the use of upper case and/or bold font, indicated to the participants that they were looking at the brand name. This also corresponds to brand name formatting seen in written medicine information leaflets, where Pires et al.[26] noted that 58.6% and 24.5% of brand names were formatted as sentence case or all upper case letters in the evaluated leaflets, respectively. The worst performing formatting combination was that seen on Label 14B where the active ingredient was presented in bold font first with the brand name included in brackets next. This was essentially the reverse of current labelling practice in Australia and is explanatory of why only 1/10 participants correctly identified the active ingredient on this particular label. The improvement in active ingredient identification for the cream labels between Round 1 and Round 2 also indicated that active ingredient and brand name formatting factored into this improvement, as the Round 2 cream label displayed more current formatting characteristics by stating the brand name first, and active ingredient specified in brackets. Thus, current labelling practice, as understood by people, impacted their ability to differentiate between the active ingredient and brand name when formatting was used that was different to current practice. These findings will have significant implications for future legislative changes to increase the prominence of active ingredient information by placing it first, before the brand name (that is, the opposite of current practice).

The active ingredient name, and perceptions of whether it was technical or not, influenced participants' ability to correctly identify the active ingredient. This was particularly obvious with the eye drops labels, where the active ingredient hypromethylmellose was correctly identified as the active ingredient, and Lubidrops as the brand name. Reliance on people's interpretation of how technical sounding a term is in order to appropriately determine an active ingredient is not ideal, and implementation of appropriate and effective formatting and content cues are needed to remove the element of "guesswork" for medicine users.

National guidelines for on-screen display of medicines information, published by the Australian Commission on Safety and Quality in Health Care, provide recommendations on presentation of active ingredient information and brand name, for example use of lower case bold for active ingredient and sentence case italics for brand name.[27] However, these recommendations do not appear to be targeted at dispensed prescription medicine labels for consumers. The present study findings suggest that the use of formatting to distinguish between the active ingredient and brand name for people is more complex than one single recommended approach. As seen, bolding of the active ingredient may in some cases lead to poorer ability to differentiate between the active ingredient and brand name. Consequently, this highlights the importance of user testing and factoring in the impact of current labelling practice on providing context for consumers. From a medication safety standpoint, prior research informing best practice in the formatting of active ingredient / brand name information is lacking, despite the importance of ensuring the active ingredient name(s) is prominently placed on medication packaging.[28] Thus, whilst font size and positioning of the active ingredient are important in increasing the prominence of the active ingredient name and assisting with its identification, key stakeholders must also be cognisant of the role and impact of other formatting, such as the use of bold and italics, on dispensed prescription medicine label information understanding.

Should labelling legislation and standards dictate that in the future active ingredient(s) information is placed first before brand name, then the evidence from this study suggests that sign-posting is necessary to educate people about the active ingredient and brand name. This will slowly change the status quo that people are used to, until changes in how active ingredient and brand name are communicated become "routine practice" and people are accustomed to the change. As seen from the Round 2 suspension labels, where the active ingredient and brand name were clearly sign-posted, this enabled all participants who evaluated the labels to find and understand this information. This observed superior label performance is a key labelling strategy and recommendation stemming from this research that would mitigate any order effects when communicating medicine name information on the label and is likely to promote better understanding. Simply placing the active ingredient first, to improve medication safety, without appropriate sign-posting, may actually be more harmful, and have a negative impact on its identification by people.

Key Recommendations

DO:

✓ Sign-posting of active ingredient and brand name on label, especially if:

1. Intending to change current practice by stating the active ingredient first
2. The brand name sounds like an active ingredient
3. The active ingredient is not noticeably technical / medical jargon-like

DO NOT:

✘ Bold the active ingredient and place the brand name in brackets

✘ Italicise the brand name (especially if presented after / below the active ingredient)

4.2 Communication of dosage information / directions for use

Overall, across all label formats, participants demonstrated satisfactory ability to find and understand the directions for use on the labels. This differs from the findings of Davis et al.[21] where a significantly higher proportion of participants understood labels that conveyed the directions for use using approximate times per day or explicit times, in comparison to labels that provided explicit dosing intervals or frequency of doses per day. Prior research has also been supportive of explicit directions for use.[22] However, the use of approximate times per day on labels may not translate to statistically significant differences in understanding when compared with people's understanding of labels that stated frequency of doses per day.[29] Differences in the study population demographics, study process, and actual wording used to convey the directions for use on the study labels between the studies may explain the disparity observed between the findings of the present study and previous research.

In the present study, no marked difference in dosage understanding was seen between the use of words or numbers to convey numerical dosage information on labels. Recommendations for prescription labelling practice,[30] as well as the national roundtable recommendations,[7] advocate the use of numbers over words when conveying numerical information. A preference for numbers however, was noted among participants in the present study. Wolf et al.[24] also noted that people suggested the use of numbers over words. Although, it should be acknowledged that there was some preference for words, in upper case (to convey numbers), as they stood out. Consequently, the use of numbers to convey numerical dosage information is advocated for retention in moving forward when refining and implementing best practice with respect to labelling within the Australian context. However, by no means does this preclude use of words to convey numbers on dispensed prescription medicine labels. The primary outcome of using numbers or words for dosage information should be to ensure that appropriate understanding and actioning is not compromised. This requires further study within the Australian context, particular for communicating certain values; for instance, Bailey et al.[31] note that people prefer the use of words to convey fractions, rather than numbers.

Key Recommendation

DO:

✓ Use numbers to convey numerical dosage quantities where appropriate

CONSIDER:

✓ Use of words where appropriate

4.2.1 Dosing scenario on pain relief – understanding of dosing interval

Variations were seen in how participants approached the pain scenario and subsequently planned dosing for their pain which had hypothetically started at 9 am. These findings were somewhat expected in light of previous research.[12] Explicit dosing intervals had varying impact on how this information was applied by participants for the pain scenario.

The label where an explicit dosing time was not included (Label 1) performed very well in relation to the pain scenario, where people tried to evenly space the doses as best as possible to take the medicine four times a day. This likely indicates that these participants had sound health literacy and recognised the importance of evenly spacing doses. Considering the phrasing used on the label is not dissimilar to what would be seen in practice on dispensed labels, this finding is also similar to that of Sahm et al.[25], who noted that similar proportions of people who had adequate health literacy were able to demonstrate understanding of directions of use when using either labels with only the number of doses to be taken per day stated ("standard" practice) or patient-centred labels that included approximate times of day.

In contrast, approximate times of day (Label 3; take 2 tablets in the morning, 2 tablets at midday, 2 tablets in the evening, 2 tablets at night) did not perform as well in terms of supporting appropriate dosing regimens in comparison to Labels 1 and 8 (take 2 tablets every 6 hours). Label 3 did not state a specific dosing interval which could prove problematic when deciding when to take the "evening" and "night" doses. People will plan medication-taking schedules around their sleep-wake day, rather than a 24-hour day, and also factor in other pragmatic considerations when interpreting directions for use on a label.[12] Furthermore, the use of the terms "evening" and "night" or "bedtime" may be synonymous for some people and lead to a shorter dose interval between these two doses, depending on the person's definition of the times of day. Interestingly, Holt et al.[23] raised the notion that taking a medicine "'morning and night' may or may not involve a correct dosage interval",[23(p.60)] for which similar findings were seen in the present study. As explicit dosage directions are advocated for use on labels,[7, 30] if a specific dosing interval as a range in hours is not provided, its absence may cause deviations and/or variations due to individual consumers' lifestyles, preferences for medication-taking routines, and importantly, the person's health literacy. The impact of communicating information may also vary between medicines and their regimen complexities[21]; for example, simpler dosing regimens such as twice-a-day dosing may lend themselves better to being labelled as "take 2 tablets in the morning and 2 tablets at night"[7(p9)], compared to a medicine to be taken four times a day. This is also reiterated by Wallace et al.[32] where there was no significant difference seen between appropriate explanations for dosing the medicine in response to a label where a dosing interval (every 12 hours) was specified versus explicit times (7 am and 7 pm).

Participants who were given an explicit dosing interval on the label for a prn medicine (i.e. every 6 hours if needed) were able to calculate and time their doses accordingly; this suggests that labels for medicines taken on an as-needed basis should continue to be explicit about dosing intervals, rather than only stating approximate times of day. This would also meet people's preferences, considering that both previous[31, 33] and present qualitative study findings highlight that people want specificity in the directions for use stated on labels. Participants' applied awareness of the maximum daily dose was also seen in a similar previous study where a comparable scenario was posed.[12] McCarthy et al.[11] however found that when compared to an alternate proposed communication approach, known as the Take-Wait-Stop strategy, a larger proportion of people exceeded the maximum daily dose when using a label that specified prn directions for use similarly worded to those evaluated in the present study. However, there was no significant difference between the label that adopted the Take-Wait-Stop strategy compared to the standard label when examining the proportion that nominated inappropriate dosing interval(s).[11] Although this study did not seek to evaluate the use of the Take-Wait-Stop strategy in full, and did not note issues in applied understanding of the maximum daily dose, it may be useful to gain further Australian-specific evidence to see whether the Take-Wait-Stop strategy would lead to a significant difference at a population level.

Impact of inclusion of a Universal Medication Schedule table together with the dosage statement on the label

Although Labels 14A and 14B included an adapted Universal Medication Schedule (UMS) table together with their respective dosage statements (similar to the labels that have been evaluated as part of previous studies[4]), the labels did not perform comparably for the pain scenario.

Label 14A (which only included approximate times of day in the UMS: morning, midday, evening, bedtime; plus the directions "Take ONE capsule four times a day (every 6 hours)"), performed poorly. Previous research has found that the inclusion of a table on the label in addition to the dosage expressed using approximate times of day did not yield an improvement in the proportion of participants understanding the directions.[3, 25] As raised by Wolf et al.,[3] difficulty in reconciling the instructions information and the table on the same label has likely contributed to the poorer applied understanding in comparison to Label 14B (which provided explicit times for taking the doses). In response to the scenario for Label 14A, participants only nominated three doses to be taken rather than four for that day. The shortening of the dosing interval in relation to doses close to bedtime was also observed in previous research.[12] Therefore, medicine information writers need to be aware that people do not think in terms of a 24-hour day, and that there is a tendency for a day to be conceptualised as the time spent awake. This reiterates the importance of finding ways to better communicate the importance of appropriately spacing dosing intervals, or ensuring a minimum time between doses, to make certain that dosing intervals are not shortened or lengthened inappropriately and/or inadvertently.

It is important to acknowledge however that Label 14A may have performed better in supporting participants' applied understanding had different scenarios been presented for consideration. For example, the scenario specified the pain started at 9 am and the table stated that one of the four doses for the day was to be taken at midday (which may be complex to reconcile considering the 6-hour dosing interval required). A finite dosing interval (for example, 6 hours rather than 4 to 6 hours) should therefore only be specified if necessary and critical for the medicine as it can cause confusion if stated in conjunction with an adapted UMS table.

Label 14B, the corresponding label which included an adapted UMS table and twice-a-day dosing, supported all participants who evaluated it to apply the information correctly. This may be due to the UMS table itself which emphasises the explicit time period when the dose(s) should be taken (for example 7 to 9 am). Furthermore, superior performance for Label 14B may also be linked to the easier twice-a-day dosage regimen. Previous research on people's understanding of various dosage instructions has highlighted that a higher proportion of correct responses occur for the once-a-day dosage instructions.[22-24] Following on from this, it should be noted that a twice-a-day dosing regimen is relatively easy in comparison and that complexities may be inherent in the use of the UMS for medicines dosed three or four times a day.

4.2.2 Dosing schedule and tabulating multiple medicines

Most issues that led to participants not being able to appropriately plan out a dosing schedule for the four hypothetical medicines were not due to the actual label being user-tested but rather, the medicine with the three times a day dosing (as stated on the show card for the participants). The dosing schedule table provided to the participants had four columns labelled: morning (7 to 9 am), midday (12 to 1 pm), evening (4 to 6 pm), bedtime (9 to 11 pm); and was similar to the UMS. It is possible that this format did not adequately support dosing of a medicine three times a day when adhering to the four times specified in the table itself. Therefore, this may have safety implications if, for instance, there is a therapeutic need to evenly space doses for such medicines (similar to UMS-related issues raised above). It is likely that the table format itself has forced participants into selecting three time slots; in this case, morning, evening, and bedtime being the most common response coded as inappropriate.

When developing the coding framework, morning, midday, and either evening or bedtime, was accepted as an appropriate response as conceptually, this was closest to an intended dosing regimen; however, if examining the specific dosing intervals themselves, they are still not ideal. This needs to be further considered if an UMS or adapted UMS label format is to be taken forward. Previous research has shown that the inability to determine appropriate dosing intervals for a "three times daily" regimen contributed towards incorrect understanding.[19] Although a UMS label will be useful to ensure the correct number of doses per day is taken, further consideration is needed on how to best present 8-hour dosing intervals in a fixed table with four "universal" times. Fixed times at which the medication needs to be taken as per the label may affect whether or not appropriate gaps between doses are observed.

Issues regarding the application of a 6-hour dosing interval were seen in both rounds of user testing. This was predominantly due to the fact that the time nominated between the evening and bedtime doses did not adhere to the 6-hour gap as per the label, which reflects pragmatic considerations when trying to fit dosing around real time schedules. Dosing every 6 hours requires conceptualisation of one day as being 24 hours and making adjustments to people's daily routine to that effect – pragmatically, for example, shortening of the dosing interval between the last two doses of a person's waking day to fit in with their nominated bedtime. By instructing the person to take each dose within a specific period (for example, Label 14B), it was possible to reduce one cognitive step in determining when dosing should occur. If an UMS or adapted UMS table is to be advocated for use, the stated time frames may not be interpreted as adhering to 6-hour dosing intervals. This may exacerbate dosing interval issues. Therefore, the widespread impact of this requires further evaluation, particularly in the view of adherence and clinical significance.

Key Recommendation

DO:

✓ State a specific dosing interval using a narrow range and incorporating some flexibility, where appropriate, for example "4 to 6 hours" rather than 6 hours

CONSIDER:

✓ A specific dosing interval, such as 6 hours, if this level of specificity is critical to the medication regimen

4.2.3 Application of cream

Several participants found specifying a fingertip amount as the amount (or dose) of cream to apply as very useful, especially when compared with no information provided on the label. This further emphasised the value of explicit directions for use on labels, as advocated in the recommendations included in the national roundtable report.[7] However, there was also some confusion about what a fingertip amount is. Expressing the amount of cream to apply using plain language, such as "pea-sized amount" instead of fingertip amount, is likely to be better understood by the majority of the population. The limitations of content that can be included on labels versus content covered as part of counselling are real life constraints to labelling; label size and content and overall impact on label usability is a delicate interplay, which was also raised by participants, that must be maximised in order to ensure optimal usability and adequate, appropriate content communicated effectively. Together, this highlights the need to do further research on how best to communicate information about the amount of cream (and other non-solid dosage forms) to apply and ensuring that dispensed prescription medicine labels are accompanied by appropriate verbal counselling.

4.3 "Standard" information content format and overall label layout

Variations in label design and format of "standard" information content had no significant impact on participants being able to determine who the medicine was for and the expiry date. However, consumer perspectives on the single column and two column label formats were mixed. In selecting a final overall label format, due consideration should be given to other factors such as whether an UMS (or UMS adapted) table will be included on the label. Such considerations will influence the label format, for example, an UMS table cannot be effectively implemented for a two column label format. Furthermore, locating information is also undoubtedly related to whether consumers have the intention to look for this information in the first place, which a user-tested label, regardless of whether a standardised format is used, should be able to adequately support.

Other key findings around the "standard" information were using the colour red, comments about the reference number, technical terms, and the expiry date.

The colour red

The preferred and perceived importance of using the colour red for medication-related warnings on the label[34] was also evident in the present study in relation to the "Keep out of reach of children" statement. Whilst participants reported a preference for the colour red, having the "Keep out of reach of children" in a different colour to the rest of the label content will necessitate a fixed label format. This may not allow for a patient-centred label, unless dispensing software and printers allow for printing in both red and black ink. Previous labelling research has noted that label printing / software constraints have impacted the ability to implement specific label formatting aspects on study labels.[29] Consequently, these constraints also have significant bearing on real-life implementation of patient-centred labelling, due to the multitude of dispensing software vendors available for use nationally as well as internationally.

Reference number

In contrast to the present study, where participants commented that they did not know what the reference number meant, studies conducted in the United States have found that people wanted the prescription refill number included at the top of the label[34] or highlighted,[33] considering the number is referred to when ordering repeats. This emphasises that context-specific labelling strategies are needed to ensure patient-centred labelling is tailored to the population.

Technical terms

Unsurprisingly, the use of technical terms such as "suspension" proved problematic. As per well-established health literacy principles, this reinforces that consumer-friendly terms should be used to maximise usability, and if unavoidable, such terms should be accompanied by appropriate explanations in plain language as best as possible.

Overall, grouping patient and medication-specific information together, and clearly separating them from information such as the pharmacy address and reference number, was well received by participants. This is in line with previous findings.[33]

Expiry date

Similar information such as the date of dispensing and the expiry date should also be separated out to minimise confusion; the qualitative feedback received from the participants revealed that the expiry date on the labels was too close to the date of dispensing.

The findings from this study can inform strategies to optimise label content and ensure that any "standard" information content included as part of the "generic" format of a label layout allow for clear understanding. Recommendation 5.2 from the 2013 roundtable report specified that "required information that is not directly related to providing instructions on use should be positioned toward the bottom of the pharmacy dispensing label".[7(p.8)] However, the evidence from the present study supports separation of patient and medication-specific information from information not directly related to use of the medication, either at the bottom of the label or on the right hand side of the two column format (where a line separates the two types of information). The two column format performed as well as labels developed around a more traditional single column format. This again emphasises the value of label formats being user tested, and evidence from such evaluations used to support subsequent recommendations.

Rather than a single standard label format (Recommendation 4.2 from the national roundtable[7]), various label formats could be considered for use, provided that people are able to find and understand the relevant information that they need. People want effective amounts of white space,[34] larger font size,[33, 34] all horizontal text on labels,[34] and appropriate use of bolding to emphasise key information such as directions for use,[33] which is in agreement with best practice labelling. Therefore, when actioning recommendations for patient-centred labelling,[7] good information writing and design, along with appropriate content and formatting / organisation should be the emphasis rather than stipulating the inclusion of "standard" information at the bottom of the label. Furthermore, when making exemplar labels widely available on platforms such as the California State Board of Pharmacy website,[35] care should be taken to ensure that they are of good quality and can be appropriately referenced by key stakeholders to ensure current practice reflects good information writing and design practice.

This study reinforces several findings from previous literature reviews,[9, 36-39] findings which have formed evidence-based labelling principles. Well established recommendations such as use of effective white spacing, large font size, selective bolding for emphasis, are still to be carried forward as they constitute good information writing and design practice. Australian research published in recent years[40, 41] have highlighted several challenges and opportunities for labelling. These findings together with the recommendations put forward from this user testing study provide Australian context-specific evidence-based findings that can be used in developing a standard for the labelling of medicines. Importantly, effective implementation of this standard should be continuously monitored and assessed, as differences between characteristics of existing prescription medicine labels when compared with guidelines have been observed,[42] and overall inconsistencies in label formatting as well as labelling practices between pharmacies.[43, 44]

Key Recommendation

DO:

✓ Follow good information writing and design principles

✓ Ensure optimal usability by user testing any label format(s) to be implemented in practice

✓ Separate patient and medicine-specific information from other details included on the label

DO NOT:

✖ Use technical jargon, for example "suspension"

4.4 Medicine strength and quantity

The worst performance regarding medicine strength was seen for Label 18 in Round 2. This was attributable to moving the quantity of the eye drops next to the brand name, and thus nearer to the medicine strength, which led to more people locating the incorrect information (i.e. quantity of 10 mL rather than strength of 1%). This should therefore be avoided on dispensed prescription medicine labels.

Whilst there was no substantial difference from the quantitative user testing findings, qualitative participant feedback indicated that medicine strength expressed as concentrations (for example 500mg/5mL) were confusing. Standard practice and current guidelines make reference to expressing medicine strengths as concentrations for oral liquid dosage forms.[45] Considering that this may not be the most consumer-friendly way of expressing medicine strengths, this needs to be further evaluated to determine more appropriate ways of communicating this information, such as using a clearer statement to explain medicine strengths, as was included on Label 15 in Round 2. Moreover, although guidelines for on-screen display of medicines information acknowledge that expressing medicine strengths as concentrations may prove difficult for people,[27] the guidelines also advocate maintaining "mg/mL" communication of medicine strength if this corresponds to how this information is communicated in other written medicine information sources. Therefore, if mg/mL expression is to be used, then this should be accompanied by an explanation of what this means for those who have lower health literacy, especially where it is important for people to be able to correctly identify the active ingredient and medicine strength (as a concentration), and use medicine strength information in dosing.

Key Recommendation

DO:

✓ Express medicine strengths using clearer statements

✓ Express quantity clearly

✓ Position medicine strength and quantity away from each other to avoid confusion

DO NOT:

✖ For liquid dosage forms, include strength (expressed as %) close to the bottle size on the label as can lead to confusion in identifying the medicine strength

✖ Express medicine strength of a liquid dosage form as a concentration alone, for example 500mg/5mL, where possible

4.5 Limitations

There are several limitations to this research. Self-selection bias may be present among study participants, due to voluntary study participation and therefore participants interested in the study have taken part.

With respect to the labels, all study labels were affixed to blank white boxes to ensure that each study dispensed prescription medicine label was the sole focus for the user testing evaluation. In practice however, particularly in community pharmacy settings, the label would typically be affixed to the primary packaging that includes regulatory body-approved information for the medicine. This study did not explore this interplay of information and how this impacts people's understanding of the relevant medicine information on the label, considering that the study medicines were fictitious. In addition, although many formatting variations were explored in this study as best as possible without adversely affecting the study design, it should be recognised that there would technically be unlimited possible combinations that could have been studied.

Despite the variety of dosage forms taken into consideration when developing the study labels, there are other dosage forms that were not evaluated as part of this labelling study. Similarly, only one specific scenario was given for tablet / capsule labels to evaluate the application of directions for use information. Consequently, evaluation of label performance in relation to other scenarios was not undertaken as this was not the sole focus of the user testing.

4.6 Future directions

Significant capacity exists for future research that builds on the research conducted as part of this study. Future research can determine best labelling practice recommendations to communicate dosage form-specific medicine information on a dispensed prescription medicine label.

Furthermore, future studies should consider evaluating the recommended labels within the broader population. Specifically, quantitative evaluation of the formatting of active ingredient and brand name information will be useful to ascertain the most effective formatting combination (for labels both affixed to blank boxes and the manufacturer-designed packaging) and how well actively sign-posting the active ingredient and brand name supports understanding among the general population.

With regards to the UMS, limited Australian research, and in particular quantitative evaluation, is currently available to support the use of the UMS within the Australian context. Additional research will be useful to build on existing US findings of UMS development and evaluation and the current study findings on the use of a dosing table on labels. An investigation into options or variations of the UMS, and the impact of its use to support the full spectrum of consumers is needed; for instance, subgroups within the population such as shift workers (also raised by Sahm et al.[25]), culturally and linguistically diverse individuals, and varying dosage regimens that fall outside the one, two, or four doses per day, should be investigated.

Future research can also consider exploring participants' ability to measure actual doses and/or actual use of the medicine based on the label content through usability testing. Importantly, further research is imperative to explore the feasibility of introducing / changing label formats in practice, as well as the impact of optimised label formats on patient outcomes such as adherence, particularly in light of previous research not demonstrating significant impact of a new label format on adherence[4, 46] and other patient-related outcomes.[47]

4.7 Conclusions

A total of 19 labels were developed based on good information writing and design principles and evaluated through two rounds of user testing by 60 participants. Overall, the majority of labels evaluated met user testing industry standards criteria, that is, a minimum of 9/10 participants were able to find the information, **and of these**, 9 participants demonstrated complete understanding for each key point of information evaluated. Label format and label size did not appear to impact participants' ability to determine the patient name and the expiry date of the medicine, the two key points of information used as measures to evaluate the "standard" information content.

Labels failed to meet industry standards criteria due to the information related to active ingredient and medicine strength, which were found by participants as either difficult to find or difficult to understand. Label design formatting did have a notable impact on active ingredient identification. Actively specifying the active ingredient and brand name through sign-posting, was the most effective labelling strategy to improve participants' ability to identify the active ingredient on the label.

In addition, use of a tabulated dosing schedule on the label was positively received by participants and may assist people with scheduling their medicines.

4.8 Recommendations

List of label characteristics to be retained, that is, DO'S

Aspect(s)	Rationale / evidence
Active ingredient / brand name formatting	
Sign-posting of active ingredient and brand name on label, especially if: 1. Intending to change current practice by stating the active ingredient first 2. The brand name sounds like an active ingredient 3. The active ingredient is not noticeably technical / medical jargon-like	• Round 2 user testing data illustrated that this improves the ability of participants to explicitly find and understand the active ingredient (and thus implicitly discern between the brand name and active ingredient)
If not explicitly specifying which is the active ingredient and which is the brand name, consider stating the brand name first followed by the active ingredient(s) in brackets	• This reflects current practice which participants appear to implicitly understand
Communication of medicine-related information	
State a specific dosing interval using a narrow range (i.e. incorporating some flexibility), for example "4 to 6 hours" rather than 6 hours	• Specificity is desired by people • 6 to 8 hours as an example provides enough specificity to allow the person to plan their daily dosing schedule • Every 6 hours for four times a day dosing may lead to deviations from the nominated gap between doses (particularly with the last night dose), as seen from user testing data. Only include one specific interval, that is, 6 hours, rather than a narrow range like 4 to 6 hours, if this level of specificity in dosing is critical to the regimen
Use numbers to convey numerical dosage quantities where appropriate	• Although no differences were seen in the user testing findings between numbers and words, participants generally liked the use of numbers therefore this is advocated for use as per existing guidelines
When expressing pack size / quantity, specify the units immediately after, for example 100 capsules not just "100"	• Improved clarity
Consider expressing medicine strengths using clearer statements	• Improved understanding
Discard-by information – express as weeks where possible, rather than days	• Although the quantitative data suggests there is no difference in participants' ability to determine when the eye drops should be discarded, participants reported (in the qualitative interviews) that weeks is easier than days. Also, this may reduce cognitive load as the need for additional conversion from number of days to weeks is mitigated.

Aspect(s)	Rationale / evidence
Design / formatting / layout	
Use bullet points for information such as explanations	• Bullet points used when explaining "empty stomach" definition were well-liked in Round 1 and Round 2 user testing
Bolding of key terms / phrases on label	• Participants liked this in both Round 1 and Round 2 user testing; bolding for emphasis is also advocated as part of good information writing and design principles. • Examples of key terms / phrases that should be bolded include the dose, dosing interval, maximum daily dose (where applicable), and other key information relevant to dosing such as "empty stomach"
Use a tabular format, where appropriate, on labels	• Appreciated by participants as the table provides clarity on dosage regimen when presented on the label
Ensure optimal usability by user testing any label format(s) to be implemented in practice	• There was no difference between the varying label formats (single column, two column) in participants being able to find and understand the "standard" information content that was evaluated (patient name and expiry date) • Rather than implementation of a one-size-fits-all format, ensure that any label format(s) are user-friendly via appropriate user testing
Separate patient and medicine-specific information from other details included on the label	• Improves clarity

List of label aspects that should be avoided, that is, DO NOT'S

Aspect(s)	Rationale / evidence
Active ingredient / brand name formatting	
Bold the active ingredient and place the brand name in brackets	• Worst formatting combination as it utilises formatting cues that people typically and spontaneously associate with the brand name, that is, bolding and order on label / non-bracketed = brand name
Italicise the brand name (especially if presented after / below the active ingredient)	• This signifies to people that it is the active ingredient and can lead to incorrect differentiation between the brand name and active ingredient (as per results of cream labels Label 2 versus Label 17 between Round 1 and 2, respectively)
Location of information on the label	
For liquid dosage forms, include strength (expressed as %) close to the bottle size on the label as can lead to confusion in identifying the medicine strength	• Confusion exhibited by participants in user testing when the bottle size was located with the medicine name
Co-locate expiry date and dispensing date	• Participants voiced confusion in Round 1; co-location can impair understanding as dispensed date is stand-alone and undefined
Communication of medicine-related information	
Express medicine strength of a liquid dosage form as a concentration alone, for example 500mg/5mL	• Although there is limited quantitative data that suggests that expressing medicine strength via stating the concentration impairs understanding, participants noted confusion in this presentation of information
Use technical jargon, for example "suspension"	• Technical terms can cause confusion

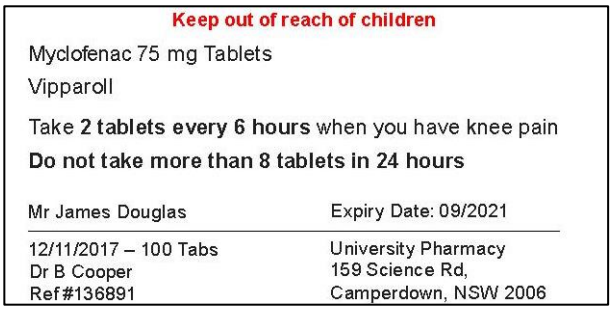
4.9 Labels recommended for quantitative evaluation

The following labels were proposed to be taken forward for evaluation in the quantitative phase of testing. These labels took into consideration the findings from Round 1 and Round 2 user testing, whereby label variables were varied and evaluated to generate evidence with respect to their impact on the ability of participants to find and understand information. Several different label formats can be put forward for evaluation, with specific labelling aspects expected to perform well regardless of the label format or how they are combined.

It should be noted that the following labels are not exhaustive combinations of label formatting aspects but rather, are foundation labels upon which further discussions can take place to arrive at a consensus as to which variables are of precedence to evaluate quantitatively. Furthermore, some aspects, although not formally evaluated in the user testing, may be considered in light of feedback received and/or research expertise when appraising all labels evaluated in the user testing, for example the variations of the dosing table with narrower time-frames; allocated space where the time to be taken can be written, among other factors.

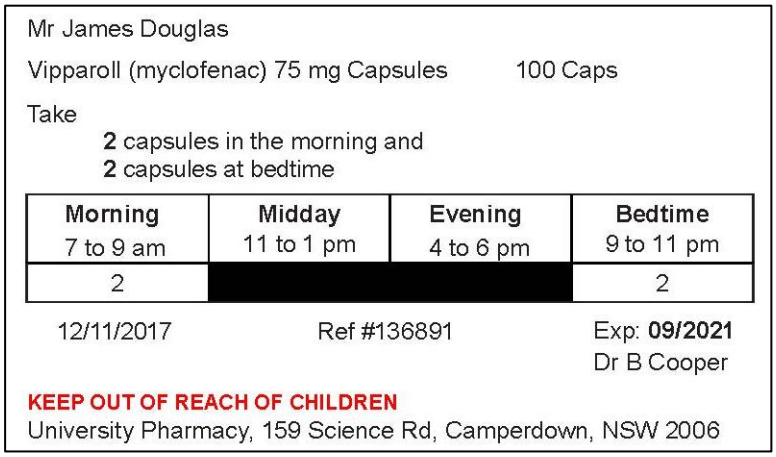
Label A

- Basic label layout



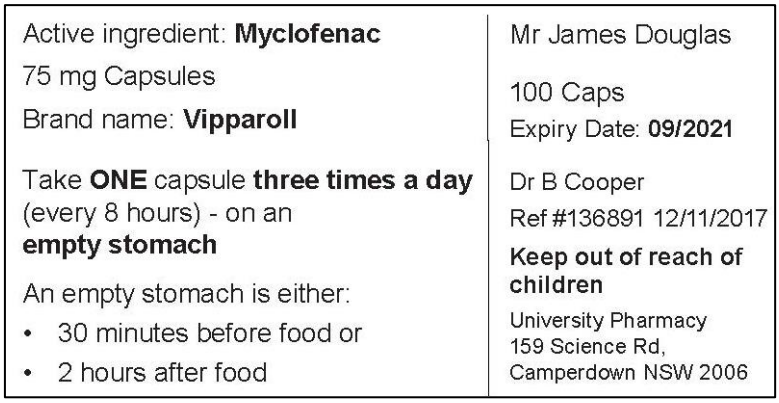
Label B

- It should be noted that a tabulated dosing schedule is not as conducive for three times a day dosing schedules, as the day is partitioned into four intervals
- Mixed opinions regarding the blacked out squares. Can carry forward if this label is evaluated quantitatively among the broader population



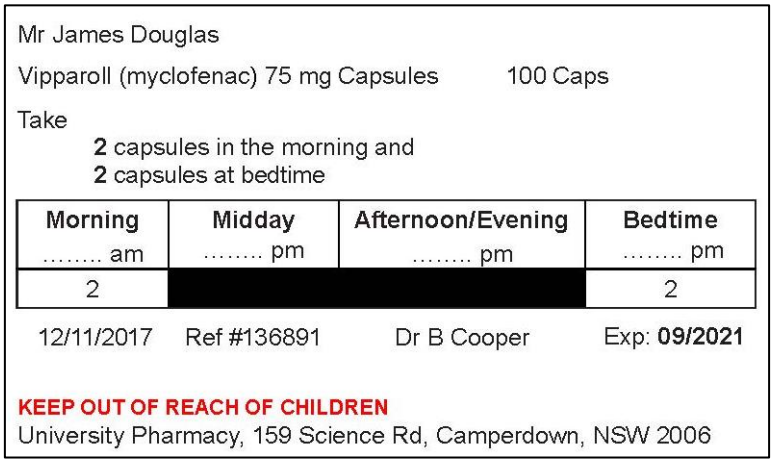
Label C

- All participants in Round 2 could find and understand the active ingredient when it was clearly sign-posted



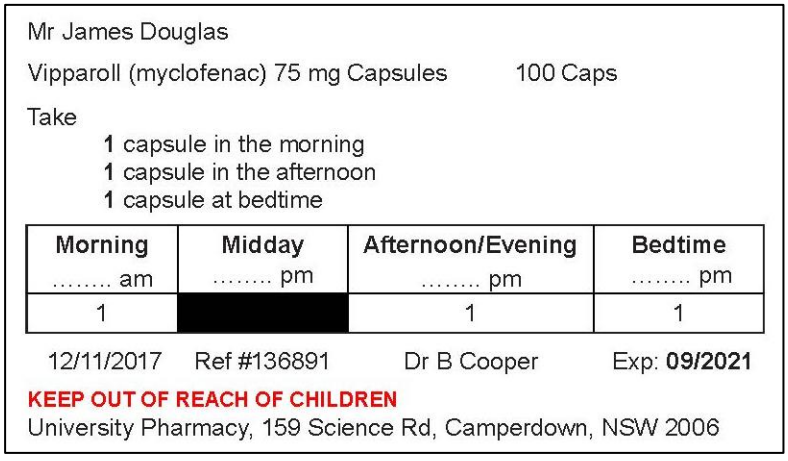
Label D

- Omission of explicit dosing times for flexibility (people advocated for flexibility, for example in the case of shift workers) – insertion of "…" as a prompt for counselling
- Evening changed to afternoon / evening as the time interval given does not match with what some people may understand as "evening"



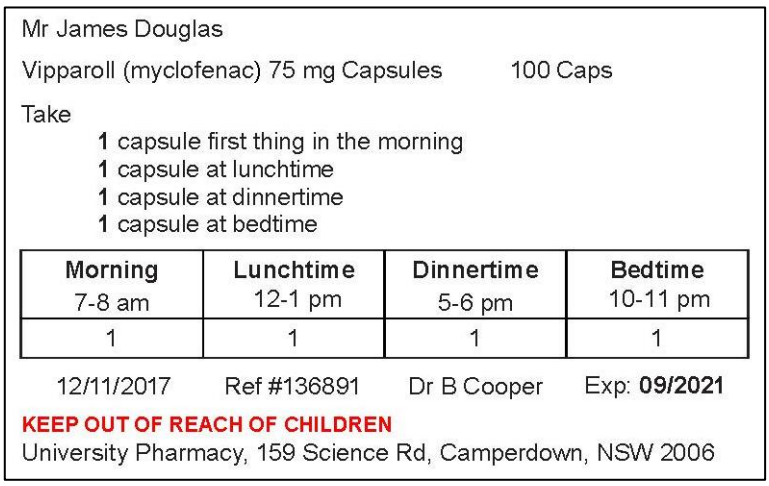
Label E

- Omission of explicit dosing times, as above
- Blacked-out square, and dosing instruction stating afternoon only, not evening (in an attempt to reinforce larger dosing interval that would be applicable for a 3-times-a-day regimen)



Label F

- Times of day changed to gravitate around mealtimes (with emphasis on taking the medicine first thing in the morning to aid correct dosing interval designation)
- Shortened time intervals corresponding to when doses can be taken proposed to improve specificity and ideally reduce the likelihood of doses being taken too close together or too far apart



Mr James Douglas

Vipparoll (myclofenac) 75 mg Capsules 100 Caps

Take
1 capsule first thing in the morning
1 capsule at lunchtime
1 capsule at dinnertime
1 capsule at bedtime

Morning 7-8 am	**Lunchtime** 12-1 pm	**Dinnertime** 5-6 pm	**Bedtime** 10-11 pm
1	1	1	1

12/11/2017 Ref #136891 Dr B Cooper Exp: **09/2021**

KEEP OUT OF REACH OF CHILDREN

University Pharmacy, 159 Science Rd, Camperdown, NSW 2006

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Appendices

Appendix 1	Justification of labels against relevant medicine information guidelines
Appendix 2	Show card and blank table of doses provided as part of the user testing questionnaire
Appendix 3	Fred labels used as stimulus material in the semi-structured interview component
Appendix 4	Participant Information Statement
Appendix 5	Participant consent form
Appendix 6	Participant demographics questionnaire
Appendix 7	Study labels evaluated in Round 1 and Round 2 user testing

Appendix 1. Justification of labels against relevant medicine information guidelines

A. Justification for labels against the National Guidelines for On-screen Display of Medicine Information

(https://www.safetyandquality.gov.au/our-work/medication-safety/electronic-medication-management/national-guidelines-for-on-screen-display-of-medicines-information/)

1. National Tall Man Lettering List

https://www.safetyandquality.gov.au/our-work/Medication-safety/Safer-naming-labelling-and-packaging-of-medicines/National-Tall-Man-Lettering-List/

The national tall man lettering list has not been used in developing the labels for Rounds 1 and 2 of the study due to the following reasons:

- The national tall man lettering list is focused on look-alike, sound-alike (LASA) medicine names; and the scope of our current project is not about differentiating between medicine names, but being able to identify and discern between an active ingredient and a brand name.
- The aim of the national tall man lettering list is to help clinicians reduce the risk of LASA medicine selection errors, whilst the aim of our study is to ensure that people can find, understand, and act on the information (in particular, the dose information) on dispensed prescription medicine labels.

2. Recommendation for Terminology, Abbreviations and Symbols used in Medicines Documentation

https://www.safetyandquality.gov.au/our-work/Medication-safety/Safer-naming-labelling-and-packaging-of-medicines/Recommendation-for-Terminology-Abbreviations-and-Symbols-used-in-Medicines-Documentation/

With reference to the Summary Sheet of the above document: (https://www.safetyandquality.gov.au/wp-content/uploads/2017/01/Recommendations-for-terminology-abbreviations-and-symbols-used-in-medicines-documentation-Summary-sheet-December-2016.pdf)

- We have addressed points 1-8, and 12-15 of the “Principles for safe, clear and consistent terminology for medicines”.
- We have not addressed point 9 of the “Principles for safe, clear and consistent terminology for medicines” due to the reasons outlined above for National Tall Man Lettering List.
- Points 10 and 11 have been addressed and varied to an extent as part of Round 1 and Round 2 label development, in line with the study objectives.
- We have adopted some of the suggested entries (with regards to dosing and frequency; units of measure/concentration; and dosage form) in the “List of safe terms, abbreviations and dose designations for medicines” as applicable and relevant to develop the labels in Round 1 and 2, and to address the study objectives.

As part of our study, we intend to determine whether participants can identify and report the active ingredient found on the label of the fictitious medicines; and thereby in the process, determine whether participants are able to accurately discern between the active ingredient and brand name. Therefore, we have used a range of design formatting, that is, italics, bold, upper case, sentence case, to determine which particular formatting would assist participants in identifying and discerning between the active ingredient and brand name.

- We have therefore followed the guidelines in the “National Guidelines for On-Screen Display of Medicines Information” in ensuring that the active ingredient and brand name are on two separate lines, but changed other design formats (as stated above).

B. Justification for labels against the Health Literacy Fact Sheet 4: Writing health information for consumers

www.safetyandquality.gov.au/wp-content/uploads/2017/07/Health-Literacy-Fact-Sheet-4-Writing-health-information-for-consumers.pdf

The above Fact Sheet was used as a reference source in developing the dispensed prescription medicine labels for the study.

C. Justification for labels against the DRAFT National guidelines for labelling of dispensed medicines

The above guidelines (Draft v5.0) as well as the Recommendations were used as a reference source for the development of the dispensed prescription medicine labels for the study. Critical information items, such as dose, were expressed in several ways in order to determine the optimal methods of conveying information for better understanding.

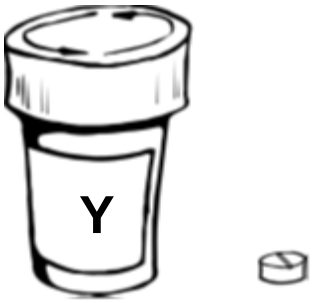
Table 1 below details our actions against the Recommendations.

Table 1. Recommendations from DRAFT National guidelines for labelling of dispensed medicines

Recommendation	Comment
1. Prominently display the most important information that consumers need to take their medicine safely and effectively	Addressed
2. Include the indication for use of the medicine whenever possible and appropriate, with consumer consent	Not wholly addressed Only one label has indication (knee pain) as part of prn dose instructions Outside the scope of this study
3. Include a 2D barcode	Not addressed Outside the scope of this study
4. Include a graphic dose matrix as a visual guide for consumers who have complex medication needs	Addressed through the use of a dosing table on a label for an oral solid dosage form
5. Ensure that label components comply with relevant national and state and territory legislation and guidelines	Addressed
6. Use a consistent and standardised format so that each element appears in the same place every time	We varied the format as this was part of the study objectives / scope
7. Present the most important information first and in greatest prominence	Addressed
8. Ensure that required information that does not relate to instructions for use is positioned towards the bottom of the label, away from dosing instructions	Addressed, through inclusion of such information towards the bottom of the label or in the right hand column across different label formats
9. Use a standard font for all pharmacy dispensing labels	Addressed
10. Use a minimum font height of 2 millimetres for all text on the label	Addressed
11. Use bold for the consumer name, active ingredient and dose, and use italics for the brand name	We have varied the formatting, wording and position as these were part of the study objectives / scope

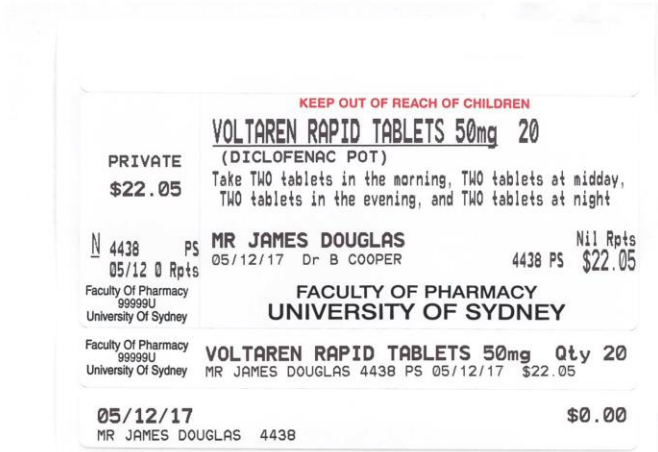
Recommendation	Comment
12. Use sentence case (capital letter only for the first word in a sentence), except for brand names	Sentence case has been used throughout except for active ingredient and brand name, as such changes were within the study objectives / scope
13. Present numbers as digits, not words, except for fractions	Addressed where applicable to address study objectives
14. Ensure that dosing instructions are explicit and standardised	Addressed
15. Use a standard label size of 102 mm × 52mm	We have varied the label size as this was part of the study objectives / scope.
16. Use clear flagging labels for smaller containers	Not applicable to this study.

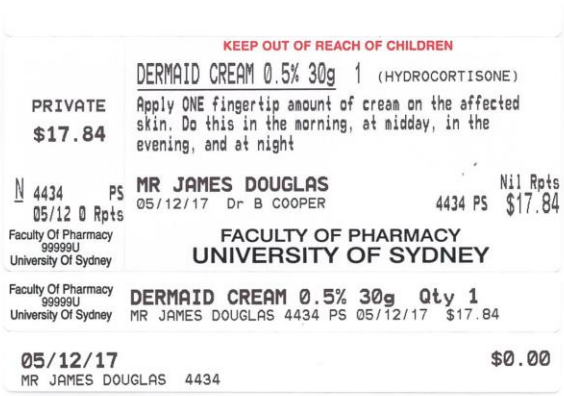
Appendix 2. Show card and blank table given as part of the user testing questionnaire

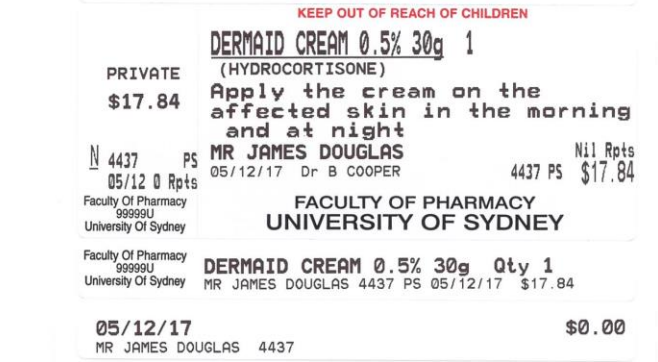
	**Medicine X** **1 tablet <u>three times a day</u>**
	**Medicine Y** **1 tablet <u>at night</u>**
	**Medicine Z** **1 tablet <u>twice a day</u>**

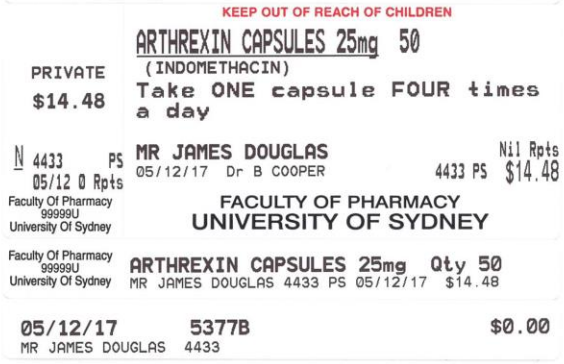
	Morning (7 to 9am)	**Midday** (12 to 1pm)	**Evening** (4 to 6pm)	**Bedtime** (9 to 11pm)
X				
Y				
Z				
Myclofenac 75mg Capsules Vipparoll				

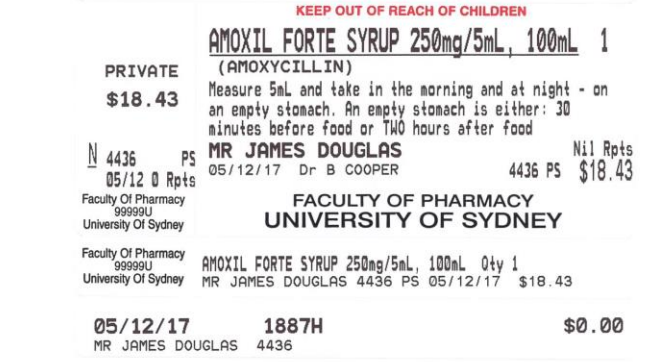
Appendix 3. Prescription labels generated using Fred Dispense, used as stimulus material for the semi-structured interview component (mapped to each study label)

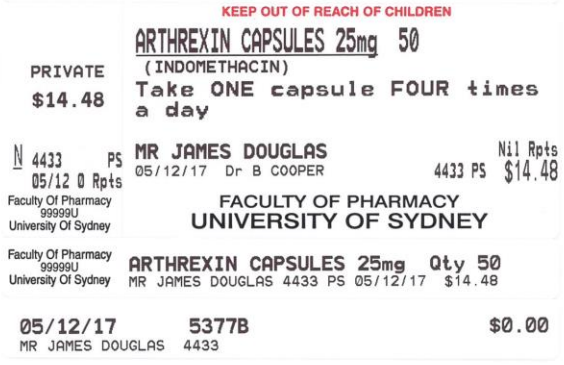

KEEP OUT OF REACH OF CHILDREN
PRIVATE
$22.05
VOLTAREN RAPID TABLETS 50mg 20
(DICLOFENAC POT)
Take TWO tablets in the morning, TWO tablets at midday, TWO tablets in the evening, and TWO tablets at night
N 4438 PS 05/12 0 Rpts
MR JAMES DOUGLAS
05/12/17 Dr B COOPER
4438 PS
Nil Rpts $22.05
Faculty Of Pharmacy 99999U University Of Sydney
FACULTY OF PHARMACY
UNIVERSITY OF SYDNEY
Faculty Of Pharmacy 99999U University Of Sydney
VOLTAREN RAPID TABLETS 50mg Qty 20
MR JAMES DOUGLAS 4438 PS 05/12/17 $22.05
05/12/17 $0.00
MR JAMES DOUGLAS 4438

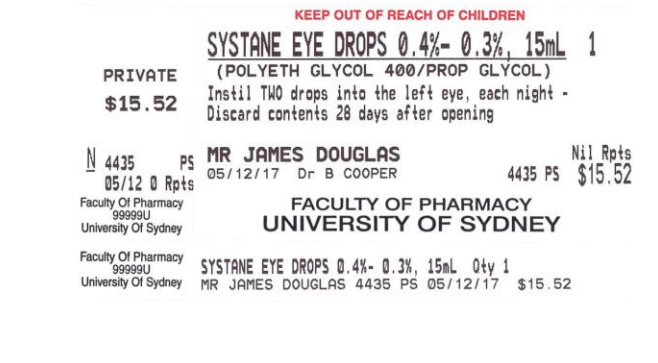

KEEP OUT OF REACH OF CHILDREN
PRIVATE
$17.84
DERMAID CREAM 0.5% 30g 1 (HYDROCORTISONE)
Apply ONE fingertip amount of cream on the affected skin. Do this in the morning, at midday, in the evening, and at night
N 4434 PS 05/12 0 Rpts
MR JAMES DOUGLAS
05/12/17 Dr B COOPER
4434 PS $17.84
Faculty Of Pharmacy 99999U University Of Sydney
FACULTY OF PHARMACY
UNIVERSITY OF SYDNEY
Faculty Of Pharmacy 99999U University Of Sydney
DERMAID CREAM 0.5% 30g Qty 1
MR JAMES DOUGLAS 4434 PS 05/12/17 $17.84
05/12/17 $0.00
MR JAMES DOUGLAS 4434

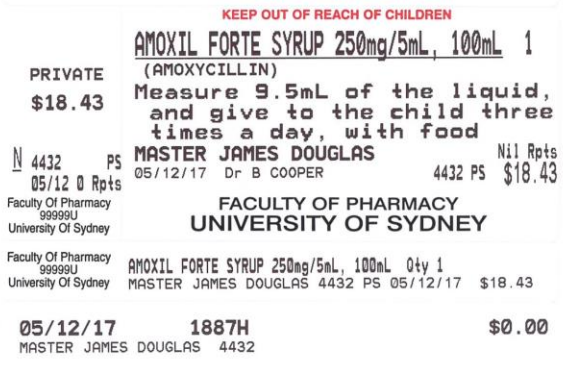

KEEP OUT OF REACH OF CHILDREN
PRIVATE
$17.84
DERMAID CREAM 0.5% 30g 1
(HYDROCORTISONE)
Apply the cream on the affected skin in the morning and at night
N 4437 PS 05/12 0 Rpts
MR JAMES DOUGLAS
05/12/17 Dr B COOPER
4437 PS
Nil Rpts $17.84
Faculty Of Pharmacy 99999U University Of Sydney
FACULTY OF PHARMACY
UNIVERSITY OF SYDNEY
Faculty Of Pharmacy 99999U University Of Sydney
DERMAID CREAM 0.5% 30g Qty 1
MR JAMES DOUGLAS 4437 PS 05/12/17 $17.84
05/12/17 $0.00
MR JAMES DOUGLAS 4437

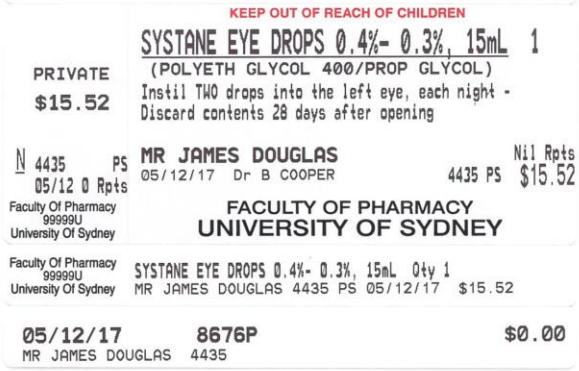

KEEP OUT OF REACH OF CHILDREN
PRIVATE
$14.48
ARTHREXIN CAPSULES 25mg 50
(INDOMETHACIN)
Take ONE capsule FOUR times a day
N 4433 PS 05/12 0 Rpts
MR JAMES DOUGLAS
05/12/17 Dr B COOPER
4433 PS $14.48
Nil Rpts
Faculty Of Pharmacy 99999U University Of Sydney
FACULTY OF PHARMACY
UNIVERSITY OF SYDNEY
Faculty Of Pharmacy 99999U University Of Sydney
ARTHREXIN CAPSULES 25mg Qty 50
MR JAMES DOUGLAS 4433 PS 05/12/17 $14.48
05/12/17 5377B $0.00
MR JAMES DOUGLAS 4433


KEEP OUT OF REACH OF CHILDREN
PRIVATE
$18.43
AMOXIL FORTE SYRUP 250mg/5mL, 100mL 1
(AMOXYCILLIN)
Measure 5mL and take in the morning and at night - on an empty stomach. An empty stomach is either: 30 minutes before food or TWO hours after food
N 4436 PS 05/12 0 Rpts
MR JAMES DOUGLAS
05/12/17 Dr B COOPER
4436 PS
Nil Rpts $18.43
Faculty Of Pharmacy 99999U University Of Sydney
FACULTY OF PHARMACY
UNIVERSITY OF SYDNEY
Faculty Of Pharmacy 99999U University Of Sydney
AMOXIL FORTE SYRUP 250mg/5mL, 100mL Qty 1
MR JAMES DOUGLAS 4436 PS 05/12/17 $18.43
05/12/17 1887H $0.00
MR JAMES DOUGLAS 4436


KEEP OUT OF REACH OF CHILDREN
PRIVATE
$14.48
ARTHREXIN CAPSULES 25mg 50
(INDOMETHACIN)
Take ONE capsule FOUR times a day
N 4433 PS 05/12 0 Rpts
MR JAMES DOUGLAS
05/12/17 Dr B COOPER
4433 PS $14.48
Nil Rpts
Faculty Of Pharmacy 99999U University Of Sydney
FACULTY OF PHARMACY
UNIVERSITY OF SYDNEY
Faculty Of Pharmacy 99999U University Of Sydney
ARTHREXIN CAPSULES 25mg Qty 50
MR JAMES DOUGLAS 4433 PS 05/12/17 $14.48
05/12/17 5377B $0.00
MR JAMES DOUGLAS 4433


KEEP OUT OF REACH OF CHILDREN
PRIVATE
$15.52
SYSTANE EYE DROPS 0.4%- 0.3%, 15mL 1
(POLYETH GLYCOL 400/PROP GLYCOL)
Instil TWO drops into the left eye, each night - Discard contents 28 days after opening
N 4435 PS 05/12 0 Rpts
MR JAMES DOUGLAS
05/12/17 Dr B COOPER
4435 PS
Nil Rpts $15.52
Faculty Of Pharmacy 99999U University Of Sydney
FACULTY OF PHARMACY
UNIVERSITY OF SYDNEY
Faculty Of Pharmacy 99999U University Of Sydney
SYSTANE EYE DROPS 0.4%- 0.3%, 15mL Qty 1
MR JAMES DOUGLAS 4435 PS 05/12/17 $15.52


KEEP OUT OF REACH OF CHILDREN
PRIVATE
$18.43
AMOXIL FORTE SYRUP 250mg/5mL, 100mL 1
(AMOXYCILLIN)
Measure 9.5mL of the liquid, and give to the child three times a day, with food
N 4432 PS 05/12 0 Rpts
MASTER JAMES DOUGLAS
05/12/17 Dr B COOPER
4432 PS
Nil Rpts $18.43
Faculty Of Pharmacy 99999U University Of Sydney
FACULTY OF PHARMACY
UNIVERSITY OF SYDNEY
Faculty Of Pharmacy 99999U University Of Sydney
AMOXIL FORTE SYRUP 250mg/5mL, 100mL Qty 1
MASTER JAMES DOUGLAS 4432 PS 05/12/17 $18.43
05/12/17 1887H $0.00
MASTER JAMES DOUGLAS 4432



KEEP OUT OF REACH OF CHILDREN

PRIVATE
$15.52

SYSTANE EYE DROPS 0.4%- 0.3%, 15mL 1
(POLYETH GLYCOL 400/PROP GLYCOL)
Instil TWO drops into the left eye, each night - Discard contents 28 days after opening

N 4435 PS
05/12 0 Rpts

MR JAMES DOUGLAS
05/12/17 Dr B COOPER 4435 PS
Nil Rpts $15.52

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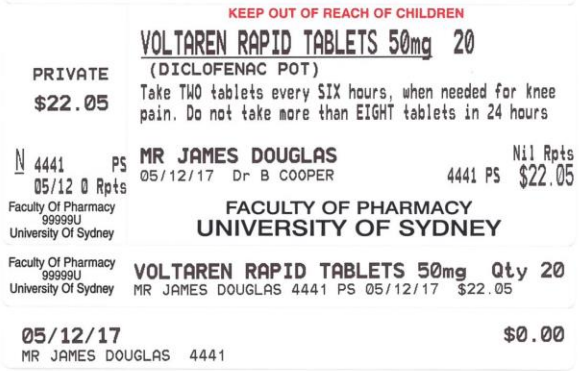
Faculty Of Pharmacy
99999U
University Of Sydney

SYSTANE EYE DROPS 0.4%- 0.3%, 15mL Qty 1
MR JAMES DOUGLAS 4435 PS 05/12/17 $15.52

05/12/17 8676P $0.00
MR JAMES DOUGLAS 4435



KEEP OUT OF REACH OF CHILDREN

PRIVATE
$22.05

VOLTAREN RAPID TABLETS 50mg 20
(DICLOFENAC POT)
Take TWO tablets every SIX hours, when needed for knee pain. Do not take more than EIGHT tablets in 24 hours

N 4441 PS
05/12 0 Rpts

MR JAMES DOUGLAS
05/12/17 Dr B COOPER 4441 PS
Nil Rpts $22.05

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University Of Sydney

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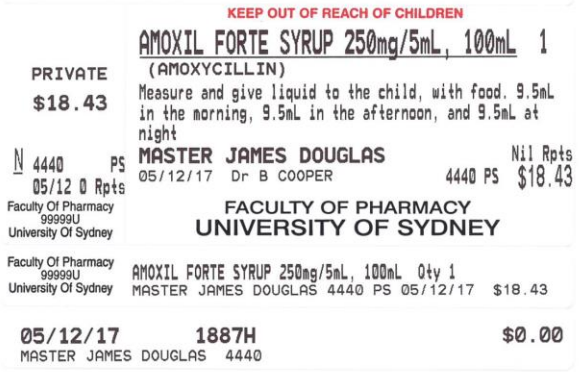
UNIVERSITY OF SYDNEY

Faculty Of Pharmacy
99999U
University Of Sydney

VOLTAREN RAPID TABLETS 50mg Qty 20
MR JAMES DOUGLAS 4441 PS 05/12/17 $22.05

05/12/17 $0.00
MR JAMES DOUGLAS 4441



KEEP OUT OF REACH OF CHILDREN

PRIVATE
$18.43

AMOXIL FORTE SYRUP 250mg/5mL, 100mL 1
(AMOXYCILLIN)
Measure and give liquid to the child, with food. 9.5mL in the morning, 9.5mL in the afternoon, and 9.5mL at night

N 4440 PS
05/12 0 Rpts

MASTER JAMES DOUGLAS
05/12/17 Dr B COOPER 4440 PS
Nil Rpts $18.43

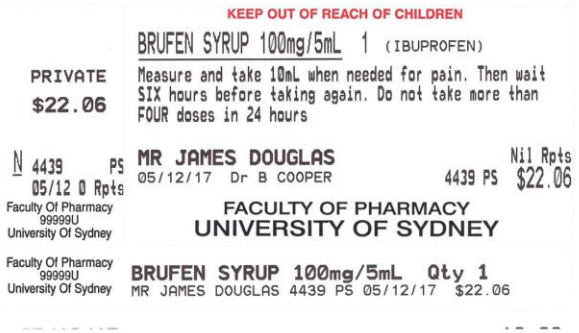
Faculty Of Pharmacy
99999U
University Of Sydney

FACULTY OF PHARMACY
UNIVERSITY OF SYDNEY

Faculty Of Pharmacy
99999U
University Of Sydney

AMOXIL FORTE SYRUP 250mg/5mL, 100mL Qty 1
MASTER JAMES DOUGLAS 4440 PS 05/12/17 $18.43

05/12/17 1887H $0.00
MASTER JAMES DOUGLAS 4440



KEEP OUT OF REACH OF CHILDREN

PRIVATE
$22.06

BRUFEN SYRUP 100mg/5mL 1 (IBUPROFEN)
Measure and take 10mL when needed for pain. Then wait SIX hours before taking again. Do not take more than FOUR doses in 24 hours

N 4439 PS
05/12 0 Rpts

MR JAMES DOUGLAS
05/12/17 Dr B COOPER 4439 PS
Nil Rpts $22.06

Faculty Of Pharmacy
99999U
University Of Sydney

FACULTY OF PHARMACY
UNIVERSITY OF SYDNEY

Faculty Of Pharmacy
99999U
University Of Sydney

BRUFEN SYRUP 100mg/5mL Qty 1
MR JAMES DOUGLAS 4439 PS 05/12/17 $22.06

Appendix 4. Participant Information Statement

THE UNIVERSITY OF SYDNEY

Faculty of Pharmacy

ABN 15 211 513 464

Parisa Aslani
Professor in Medicines Use Optimisation

Room N502
Pharmacy and Bank Building A15
The University of Sydney
NSW 2006 AUSTRALIA
Telephone: +61 2 9036 6541
Facsimile: +61 2 9351 4391
Email: parisa.aslani@sydney.edu.au
Web: http://www.sydney.edu.au/

PARTICIPANT INFORMATION STATEMENT
Developing standards for labelling dispensed medicines

(1) What is this study about?

This study is about different label designs for medicines that are obtained from a pharmacy on a doctor's prescription. We are interested to see how well different label designs help people find, understand and act on the medicine information that is included in them. We would also like to explore your opinions on different label designs. Your feedback will help us improve this information for the future and develop guidelines on standardisation of labels in Australia.

This Participant Information Statement tells you about the research study. Knowing what is involved will help you decide if you want to take part in the research. Please read this sheet carefully and ask questions about anything that you don't understand or want to know more about.

Participation in this research study is voluntary. So it's up to you whether you wish to take part or not.

By giving your consent to take part in this study you are telling us that you:
✓ Understand what you have read
✓ Agree to take part in the research study as outlined below
✓ Agree to the use of your personal information as described

(2) Who is running the study?

The study is being carried out by the following researchers:

- Professor Parisa Aslani, The University of Sydney
- Dr Vivien Tong, The University of Sydney
- Professor DK Theo Raynor, University of Leeds (UK)
- Ms Diana Shipp, Australian Commission on Safety and Quality in Health Care
- Mr Daniel Lalor, Pharmacy Department, Canberra Hospital and Health Services
- Ms Jackie Crofton, Department of Pharmacy, Royal Darwin Hospital Royal Darwin Hospital
- Ms Joanne Young, The Royal Melbourne Hospital
- Ms Sophie Carter, The University of Sydney

Professor DK Theo Raynor is also the academic advisor and co-founder of Luto Research Ltd, a company which offers health information testing services.

This study has received funding from the Australian Commission for Quality and Safety in Health Care.

THE UNIVERSITY OF SYDNEY

(3) What will the study involve for me?

The interview session will be held at the Faculty of Pharmacy, University of Sydney. On the day, we will confirm your details and collect some extra information about you.

You will be given a label (which has been placed on a box) that comes with a prescription medicine and asked to read the information on the label. Once you have finished reading the information, we will then ask you some questions about the information you have read. You will have the label in front of you to look at when answering these questions. Please keep in mind that we are not testing you or your memory. We are testing the information on the label to see how easy it is for you to find and understand this information about the medicine.

You will then be given another two labels, asked to read the information on the two labels, and asked two further questions about these labels, in the same manner as with the first label.

In the second half of the interview, we would like to know what you thought about the medicine information that you have helped us test. We would also like to find out what you think about other different label designs and get an understanding of what needs to be improved in future. With your permission, we will audio-record the entire session.

(4) How much of my time will the study take?

Each interview session may take approximately 1 hour.

(5) Who can take part in the study?

You are able to participate in this study if you:

- Are 18 years or older;
- Are comfortable with reading and speaking English, without needing the help of another person, such as a translator.

(6) Do I have to be in the study? Can I withdraw from the study once I've started?

Being in this study is completely voluntary, which means that you do not have to participate in this study if you do not want to. If you agree to participate, you can withdraw at any time without affecting your relationship with the researchers involved in this project at The University of Sydney. You may stop the interview at any time if you do not wish to continue. The audio recording will be deleted and the information you have provided will not be included in the study.

(7) Are there any risks or costs associated with being in the study?

Aside from giving up your time, we do not expect that there will be any risks or costs associated with taking part in this study.

(8) Are there any benefits associated with being in the study?

This study may have direct and indirect benefits to you. You will receive $40 at the end of the session for your time. Indirectly, your responses will help us gain a better picture of how well prescription medicine labels provide medicine information to people and how we can improve them.

THE UNIVERSITY OF SYDNEY

(9) What will happen to information about me that is collected during the study?

In this study, with your permission, we will be audio recording the interview session and your responses. We will also collect some other demographic details to help us get a better understanding of those who will be coming in for these interview sessions.

All the information we collect from you will be strictly confidential and only the researchers will have access to this information. It will be stored securely for 5 years in our office at the University of Sydney and after this time, it will be destroyed. Reports about this study may be published or presented at conferences, but individual participants will not be identifiable.

By providing your consent, you are agreeing to us collecting personal information about you for the purposes of this research study. Your information will only be used for the purposes outlined in this Participant Information Statement, unless you consent otherwise.

(10) Can I tell other people about the study?

Yes, you are welcome to tell other people about the study.

(11) What if I would like further information about the study?

When you have read this information, Vivien Tong will be available to discuss it with you further and answer any questions you may have. If you would like to know more at any stage during the study, please feel free to contact Vivien Tong on: (02) 9036 7270 (telephone) or at vivien.tong@sydney.edu.au (email).

(12) Will I be told the results of the study?

You have a right to receive feedback about the overall results of this study. You can tell us that you wish to receive feedback by indicating this on the consent form. You will receive feedback in the form of a one page summary after the study has finished and the data has been analysed.

(13) What if I have a complaint or any concerns about the study?

Research involving humans in Australia is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this study have been approved by the HREC of the University of Sydney *[2017/620].* As part of this process, we have agreed to carry out the study according to the *National Statement on Ethical Conduct in Human Research (2007).* This statement has been developed to protect people who agree to take part in research studies.

If you are concerned about the way this study is being conducted or you wish to make a complaint to someone independent from the study, please contact the university using the details outlined below. Please quote the study title and protocol number.

The Manager, Ethics Administration, University of Sydney:

- **Telephone:** +61 2 8627 8176
- **Email:** ro.humanethics@sydney.edu.au
- **Fax:** +61 2 8627 8177 (Facsimile)

This information sheet is for you to keep.

Appendix 5. Participant consent form

Faculty of Pharmacy

ABN 15 211 513 464

Parisa Aslani
Professor in Medicines Use Optimisation

Room N502
Pharmacy and Bank Building A15
The University of Sydney
NSW 2006 AUSTRALIA
Telephone: +61 2 9036 6541
Facsimile: +61 2 9351 4391
Email: parisa.aslani@sydney.edu.au
Web: http://www.sydney.edu.au/

PARTICIPANT CONSENT FORM

Developing standards for labelling dispensed medicines

I, ... [PRINT NAME], agree to take part in this research study.

In giving my consent I state that:

1. I understand the purpose of the study, what I will be asked to do, and any risks/benefits involved.
2. I have read the Participant Information Statement and have been able to discuss my involvement in the study with the researchers if I wished to do so.
3. The researchers have answered any questions that I had about the study and I am happy with the answers.
4. I understand that being in this study is completely voluntary and I do not have to take part. My decision whether to be in the study will not affect my relationship with the researchers or anyone else at the University of Sydney now or in the future.
5. I understand that I can withdraw from the study at any time.
6. I understand that I may stop the interview at any time if I do not wish to continue, and that unless I indicate otherwise any recordings will then be erased and the information provided will not be included in the study. I also understand that I may refuse to answer any questions I don't wish to answer.
7. I understand that personal information about me that is collected over the course of this project will be stored securely and will only be used for purposes that I have agreed to. I understand that information about me will only be told to others with my permission, except as required by law.
8. I understand that the results of this study may be published, and that publications will not contain my name or any identifiable information about me.
9. I understand that I will be given $40 for my time at the end of the interview session if I choose to complete the session today.
10. I consent to:
    - **Audio-recording** YES ☐ NO ☐

Would you like to receive feedback about the overall results of this study?

YES ☐ **NO** ☐

If you answered **YES**, please indicate your preferred form of feedback and address:

☐ Postal: _____

_____

☐ Email: _____

.....

Signature

.....

PRINT name

.....

Date

Appendix 6. Participant demographics questionnaire

THE UNIVERSITY OF SYDNEY

Appendix 6 – Additional demographics collection form

Country of Birth: Australia ❒

Overseas ❒ Please specify: _____

Main language spoken at home:

English ❒

Other ❒ Please specify: _____

Other language(s) spoken at home:

English ❒

Other ❒ Please specify: _____

None ❒

Health Information Understanding

1. How confident are you filling out medical forms by yourself?

Extremely	Quite	Somewhat	A little	Not at all
❒	❒	❒	❒	❒

2. How often do you have someone help you read written medicine information?

None of the time	A little of the time	Some of the time	Most of the time	All of the time
❒	❒	❒	❒	❒

3. How often do you have problems learning about your medical condition or medicines because of difficulty reading and understanding written information?

None of the time	A little of the time	Some of the time	Most of the time	All of the time
❒	❒	❒	❒	❒

Thank you for your responses.

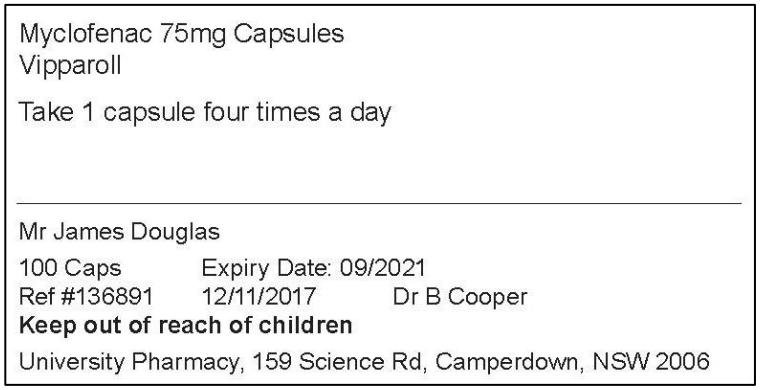
Developing standards for labelling dispensed medicines
Additional demographics collection form
Version 01- 260617

Page 1 of 1

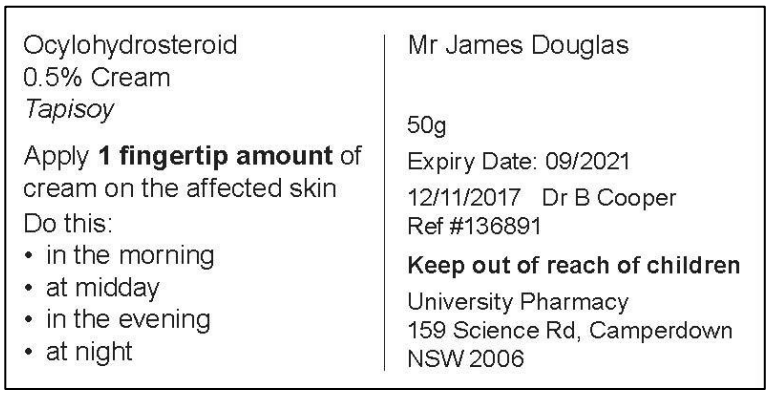
Appendix 7. Study labels evaluated in Round 1 and Round 2 user testing

Round 1 labels

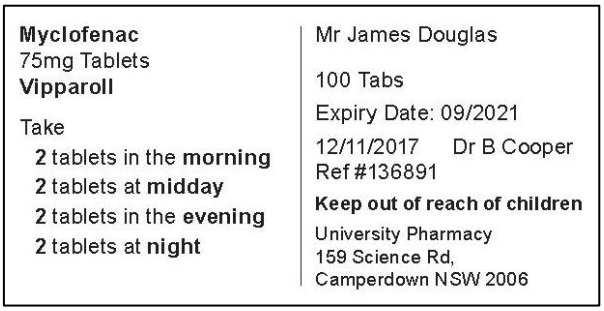
Label 1
(102 mm x 52 mm)



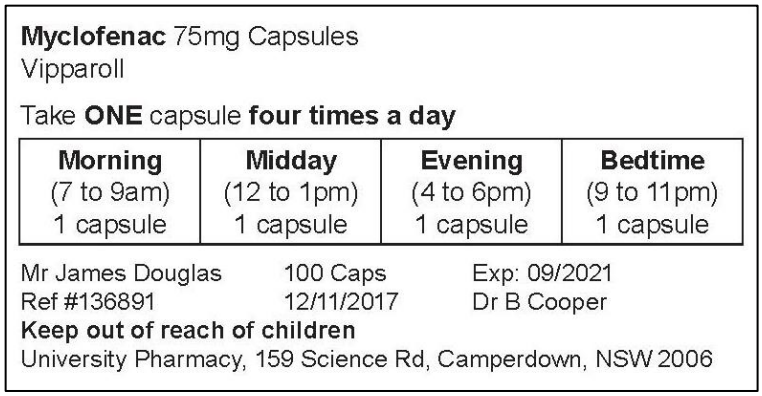
Label 2
(102 mm x 52 mm)



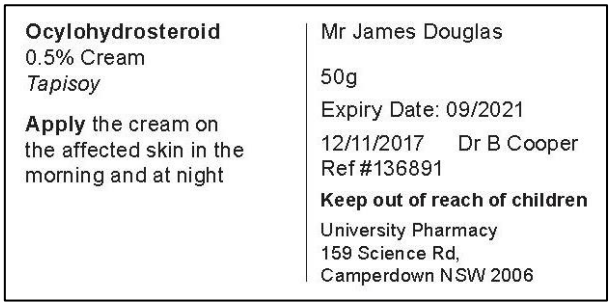
Label 3
(80 mm x 40 mm)



Label 4
(102 mm x 52 mm)

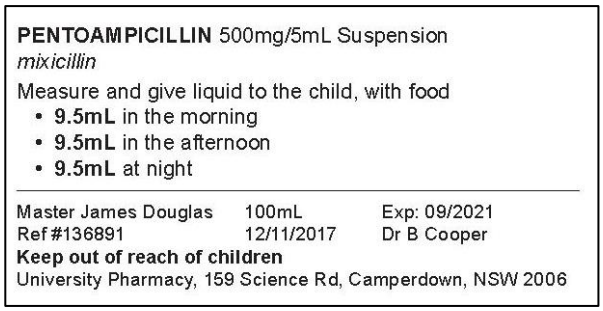


Label 5
(80 mm x 40 mm)

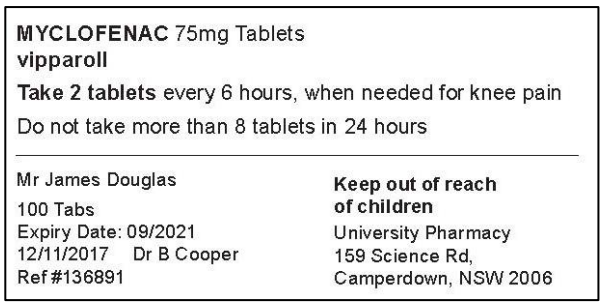


Label 6
(102 mm x 52 mm)

Label 7
(80 mm x 40 mm)



Label 8
(80 mm x 40 mm)



Label 9
(80 mm x 40 mm)

Myclofenac 75mg/5mL Suspension
vipparoll

Measure and take 10mL when needed for pain
Then **wait** 6 hours before taking again

Do not take more than 4 doses in 24 hours

100mL Exp: 09/2021 Mr James Douglas
Ref #136891 12/11/2017 Dr B Cooper
Keep out of reach of children
University Pharmacy, 159 Science Rd, Camperdown, NSW 2006

Label 10
(102 mm x 52 mm)

Pentoampicillin
500mg/5mL Suspension
MIXICILLIN

Measure 5mL and take in the **morning** and at **night** - on an empty stomach

An empty stomach is either:
- 30 minutes before food or
- 2 hours after food

Mr James Douglas

100mL
Expiry Date: 09/2021
12/11/2017 Dr B Cooper
Ref #136891
Keep out of reach of children
University Pharmacy
159 Science Rd, Camperdown
NSW 2006

Label 11
(102 mm x 52 mm)

HYPROMETHYLMELLOSE
1% Eye Drops
LUBIDROPS

Put **2 drops**
into the left eye,
each night

Throw away the bottle
28 days after opening it

Mr James Douglas

10mL
Expiry Date: 09/2021
12/11/2017 Dr B Cooper
Ref #136891
Keep out of reach of children
University Pharmacy
159 Science Rd, Camperdown
NSW 2006

Label 12
(80 mm x 40 mm)

Hypromethylmellose
1% Eye Drops
Lubidrops

Put **2 drops** into the **left eye**, each **night**

Throw away the bottle
28 days after opening it

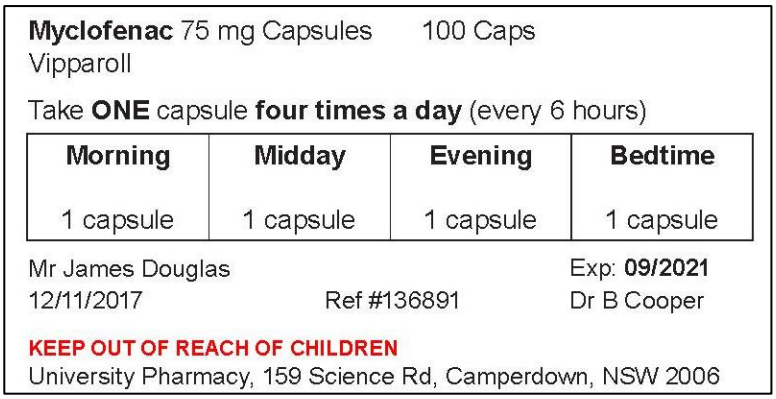
Mr James Douglas

10mL
Expiry Date: 09/2021
12/11/2017 Dr B Cooper
Ref #136891
Keep out of reach of children
University Pharmacy
159 Science Rd,
Camperdown NSW 2006

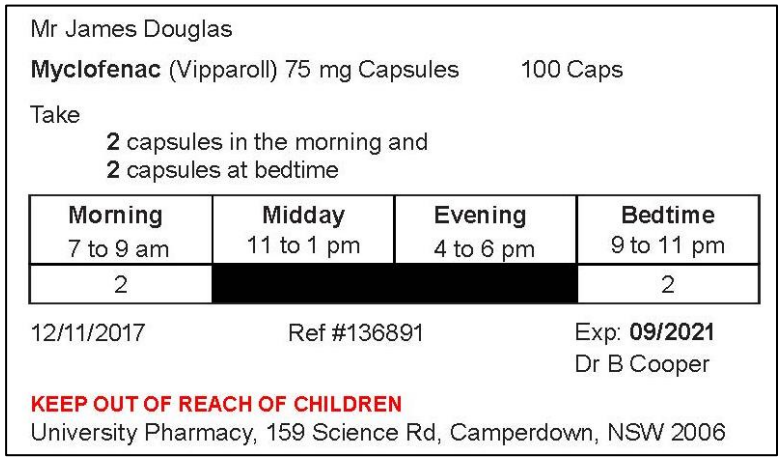
Round 2 labels

Label 13
(80 mm x 40 mm)

Label 14A
(102 mm x 52 mm)

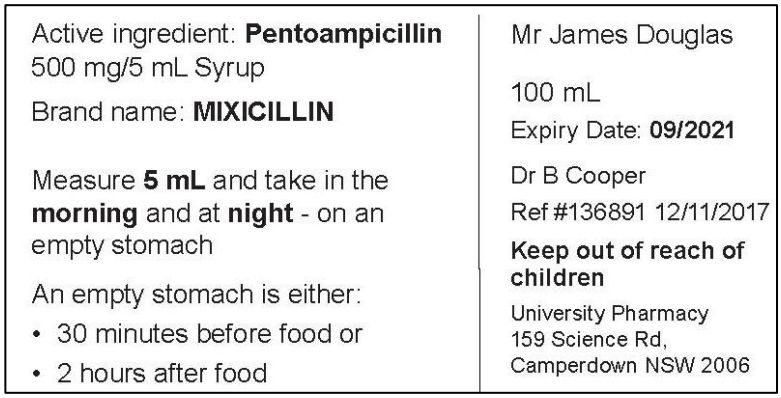


Label 14B
(102 mm x 58 mm)

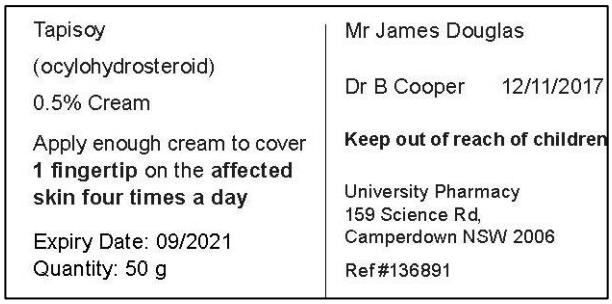


Label 15
(102 mm x 52 mm)

Label 16
(102 mm x 52 mm)



Label 17
(80 mm x 40 mm)



Label 18
(80 mm x 40 mm)