AUSTRALIAN COMMISSION
ON SAFETY AND QUALITY IN HEALTH CARE

National standard for labelling **dispensed medicines**

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Abbreviations and acronyms

Acronym	Term
AMT	Australian Medicines Terminology
ARTG	Australian Register of Therapeutic Goods
CAL	cautionary advisory label
CALD	culturally and linguistically diverse
CMI	Consumer Medicine Information
INN	International Nonproprietary Name
PBA	Pharmacy Board of Australia
PRN	pro re nata (when needed)
PSA	Pharmaceutical Society of Australia
REALM	Rapid Estimate of Adult Literacy in Medicine
TGA	Therapeutic Goods Administration
TGO	Therapeutic Goods Order
UMS	Universal Medication Schedule

Summary

Consumers need a good understanding of how and when to take a medicine. This can help them to use their medicines safely and help achieve the best possible health outcomes. Misunderstanding of how to use medicines can lead to unintentional misuse, which may result in harm or adverse health outcomes.

The design and content of information on a medicine label influences how well the consumer understands the information, especially for consumers with low health literacy. Standardised and consistent presentation of medicine-related information on dispensed medicine labels has the potential to improve health outcomes.

This standard is for all health professionals who dispense medicines, including pharmacists, pharmacy technicians, nurse practitioners, general practitioners, optometrists and dentists. It is based on best practice and evidence-based principles, recommendations published by the Australian Commission on Safety and Quality in Health Care (the Commission)[1], and further informed by user testing and hospital evaluation of prototype labels, and stakeholder consultation.

This standard provides guidance for labelling dispensed medicines clearly and consistently. Guidance includes what information to include on the label, where it should be placed on the label, and how it should be formatted to optimise consumer understanding for safe and quality medicine use.

This *National Standard for Labelling Dispensed Medicines* describes standards and supporting strategies that align with legislative requirements. This standard should be considered as part of dispensing best practice and applied in addition to these requirements.

Summary of standards

See Section 4 for a full description of the standards with examples.

Standard	Details
Standard 1	Prominently display the information that consumers need to take their medicine safely and effectively
Standard 2	Use a standardised format and order so that each element appears in the same place every time
Standard 3	Signpost and display the active ingredient name first, followed by the brand name
Standard 4	Include strength, as a quantity of active ingredient(s) with the relevant unit(s) of measure, after each active ingredient name. Use a clear statement of strength for liquid medicines
Standard 5	Include the formulation in full
Standard 6	Use numerals (digits) for dosage quantities, except for fractions
Standard 7	Use explicit and clear dosing instructions
Standard 8	Include the indication for use of the medicine, whenever possible, and consider consumer confidentiality
Standard 9	Include the maximum dose, if relevant
Standard 10	Express the pack size or quantity with units and place in a separate location from the strength
Standard 11	Express discard-by information with a date, if possible
Standard 12	Include a machine-readable verification code on the dispensed label to allow verification of the medicine during the dispensing process

Summary of supporting strategies

The following supporting strategies are optional for dispensed medicine labels. Health service organisations are encouraged to put these strategies in place alongside the standards. See Section 5 for a full description of the supporting strategies, with examples.

Supporting strategy	Details
Supporting strategy 1	Tabulate or list the dosage and frequency for medicines with complex dose schedules
Supporting strategy 2	Specify the dosing interval using a narrow range or explicit dose times
Supporting strategy 3	Include essential instructions from cautionary advisory labels
Supporting strategy 4	Use a standard sans serif font
Supporting strategy 5	Use a minimum font height of 4 mm for all text on the label
Supporting strategy 6	Use bold type for emphasis
Supporting strategy 7	Use sentence case for all label text unless otherwise required by legislation
Supporting strategy 8	Use a minimum label size of width 80 mm × height 40 mm
Supporting strategy 9	Use transparent flag labels for smaller containers

1 Introduction

Labels for dispensed medicines are important for communicating medicine-related information to consumers and ensuring effective medicine use. The dispensed medicine label must include the essential information the consumer needs to take their medicines safely and effectively.

All dispensed medicines are legally required to have a label before being provided to the consumer. Mandated requirements vary between states and territories, but include the consumer's name; medicine name, strength and dose form; date of dispensing; and the name and address of the dispensing pharmacy.

Labels are created according to the medicine information in a prescription. The label is applied to medicine packaging at the point of dispensing. This is usually done by a pharmacist but may also be done by other health professionals – for example, pharmacy technicians, nurse practitioners, general practitioners, optometrists or dentists.

The label complements the consumer's interaction with clinicians. Consumers should always have the option to receive verbal counselling from their clinician about how to use a medicine safely and effectively. The dispensed medicine label provides customised information about the medicine and how the consumer should use it, at the point of use. The label is especially important if the consumer has not received more detailed written medicine-related information, or if they cannot recall the verbal information provided to them by their clinician.

The content and quality of label information affects how well the consumer understands the information, especially for consumers with low health literacy.[2] Clear, unambiguous medicine-related information is easier for consumers to understand and follow. Misunderstanding of how and when to take a medicine, and for how long, can lead consumers to unintentionally misuse their medicines. This may result in suboptimal or adverse health outcomes.

Consumers can access further information about their medicines through a number of sources, including:

- Manufacturer's primary pack
- Consumer Medicine Information (CMI) leaflets, required by legislation for all prescription medicines
- Medicines lists, provided by the pharmacy or within discharge summaries
- Electronic health records – for example, My Health Record
- Mobile medication apps – for example, NPS MedicineWise app
- Medicine information in Aboriginal and Torres Strait Islander languages, and culturally and linguistically diverse (CALD) groups – for example, the Remote Primary Health Care *Medicines Book*
- Specialty medicine-related information websites – for example, Choice and Medication printable leaflets for psychotropics.

Consumers have access to information about their medicines from several sources. However, the label on a dispensed medicine may be the only place the consumer receives personalised instructions to refer to at the point of use.

The *Australian National Medication Safety and Quality Scoping Study*[3] published in 2009 acknowledged that dispensed medicine labels can contribute towards medication errors, advocating for the implementation of dispensed medicine labelling standards. The scoping study acknowledged the dispensing guidelines that reference labelling by organisations and peak bodies – for example, the Pharmaceutical Society of Australia (PSA) and the Pharmacy Board of Australia (PBA). However, these dispensing guidelines have limited detail on standardising information that can help maximise the readability and usability of a label. This labelling standard is designed to help fill this gap.

Standardised, consistent presentation of medicine-related information across all consumer resources has the potential to improve health outcomes. Organisations such as NPS MedicineWise, the Consumers Health Forum, and state- and territory-based consumer peak bodies provide important sources of medicine-related information for consumers. They also support consumers to improve their understanding of medicine labels. A standardised format for dispensed medicine labels is likely to assist these organisations in consistent messaging across their resources for consumers.

This document refers to the term 'active ingredient'. It is acknowledged that the term 'generic medicine' is used in some international jurisdictions, and this should be considered when accessing other guidelines that may refer to the generic name within the dispensing process.

1.1 Health literacy and ability to read and understand labels

Health literacy relates to how people understand information about health and health care, how they apply that information to their lives, use it to make decisions and act on it.[2] Health literacy is important because it enables people to take action to improve the safety and quality of their own health and the health of people they provide care for.

Health literacy can be separated into two components[2]:

- Individual health literacy – the skills, knowledge, motivation and capacity of a person to access, understand, appraise and apply information to make effective decisions about health and health care, and take appropriate action
- The health literacy environment – the infrastructure, policies, processes, materials, people and relationships that make up the health system and impact the way that people access, understand, appraise and apply health-related information and services.

Not all Australian adults are able to access, understand and apply health-related information, or navigate health services. There is a high probability that a large proportion of consumers have some difficulty understanding the instructions on labels[4], which may lead to unintentional misuse of medicines.

The 2018 Australian *National Health Survey: Health literacy*[5] reported that only 39% of people found it always easy to understand health information well enough to know what to do. This included being able to accurately follow instructions from health professionals, and to read and understand all the information on medicine labels.

Consumer understanding of dispensed medicine labels

Studies on the quality and content of dispensed medicine labels have found substantial gaps in consumer understanding of their medicines and how to use them.[6-8] One study found that, using the label instruction 'Take two tablets by mouth twice daily', only 61% of consumers could correctly identify how many tablets to take each day.[7] This increased to 89% when the instructions were changed to 'Take 2 pills in the morning and 2 pills in the evening'.[8]

Consumer user testing and quantitative evaluation of prototype dispensed labels informed the development of this standard (see Section 2.2). This generated evidence for the presentation of information to support the consumer's ability to find and understand key medicine-related information.

Consumer difficulties in reading dispensed medicine labels

Factors that impact readability of labels include font size and style, spacing between words, use of colour and consistency of layout. An Australian study found that 20% of consumers had difficulty reading the dispensed medicine label.[9] Ease of reading can be affected by visual impairment[10], as well as the use of colour that decreases contrast and legibility.[11]

Differences in language, social support and access to health care can affect medication adherence and health outcomes. Consequently, due consideration is required when communicating medicine information among different groups within the Australian population, such as Aboriginal and Torres Strait Islander people and people from CALD backgrounds, to ensure appropriate understanding of medication use.

Impact of health literacy on consumer-related outcomes relevant to dispensed medicine labels

Health literacy is fundamental for medicine-related information on labels to be appropriately understood and actioned by consumers. Studies have evaluated people's understanding of instructions for use relevant to dispensed medicine labels[7,12-17] or cautionary advisory labels (CALs)[18-20] in relation to health literacy levels.[21,22] A higher proportion of participants with low literacy misunderstood instructions for use[7,12,17] and CALs[19] compared with those with marginal or adequate literacy according to the Rapid Estimate of Adult Literacy in Medicine (REALM) tool.[21] Low and marginal literacy levels were also risk factors for misunderstanding instructions[7,13,17], and low literacy levels were a predictor of misunderstanding CALs.[19,20]

Participants with low literacy were more likely to understand instructions for use expressed with explicit times of day (morning, noon, evening, bedtime) than the number of doses to be taken per day (standard practice).[14] Adherence also improved in limited-literacy consumers when explicit times of day were used.[15]

1.2 Variation in the design, content and wording of dispensed labels

Studies in Canada[23], the United States[24-26] and Sri Lanka[27] have identified differences in the design, content and wording characteristics of dispensed medicine labels. Variations in design included font size (inconsistent and often below the recommended minimum size), use of upper-case text instead of sentence case, suboptimal spacing and not using left-aligned text.[23-25]

Content included on labels may be incomplete, and can vary between hospital and community pharmacy settings and dosage forms.[27] Instructions for use can be communicated in different ways on labels.[24,26] For example, a study of 20 pharmacies in the United States found that instructions for use were communicated in 16 unique ways for amoxicillin, and 14 unique ways for prednisolone.[24] Important medicine-specific information can been omitted from dispensed labels, such as how often the medicine should be taken[26], or the expiry date.[24]

Similar issues are relevant to the Australian context. In Australia, the wording of CALs is maintained by the PSA as guidance in the *Australian Pharmaceutical Formulary and Handbook*.[28] However, the use of CALs can vary.[24,25]

2 Scope and development of the standard

2.1 Scope of the standard

This standard for labelling dispensed medicines has been developed to guide the format and content of medicine-related information on the dispensed medicine label. This will help to ensure that all consumers – particularly those with low health literacy levels – can locate and understand the information about how to take their medicines safely and effectively.

The standard is intended for health professionals who create a label according to a prescription, print and attach the label to the manufacturer's primary pack and/or secondary packaging, and provide it to the consumer at the point of dispensing. This includes dispensing by pharmacists, pharmacy technicians, nurse practitioners, general practitioners, optometrists and dentists.

The standard relates to all the information on the label, including the information the consumer needs to take their medicine safely and effectively. These details may also be important to communicate with carers, nursing staff and others. The standard should be applied in parallel with any state and territory legislative requirements (Section 3).

This standard covers oral solid and liquid dose forms, which are the most common formulations of medicines.

Many of the principles identified in this standard apply to other areas and this is reflected in some of the examples. However, this standard does not cover the following:

- **Dose forms –** Dose forms other than oral solid and liquid dose forms, such as eye drops, creams and inhalers. These dose forms were not user tested. However, the principles in this standard apply across dose forms, and this is demonstrated in some of the label examples that follow

- **Warning and advisory labels**
  - mandatory warning labels listed in the Standard for the Uniform Scheduling of Medicines and Poisons[29]
  - the wording and presentation of CALs in accordance with guidance in the *Australian Pharmaceutical Formulary and Handbook*[28]

- **Electronic devices and displays**
  - medicine-related information in the dispense and consumer views of electronic health records, including My Health Record (for more information, see the *National Guidelines for On-Screen Display of Medicines Information*[30])
  - display of medicine-related information for consumers on mobile devices, including medicine list apps

- **Visual aids and other types of labelling**
  - visual aids, such as pictograms or icons, which may help understanding if they are simple; however, they require training and education for health professionals, and education for consumers on how to use them – there is insufficient evidence to support their routine use

- labels on medicines for hospital inpatient use and which may continue to be used on discharge from hospital
- labelling on pharmacy-supplied blister packs and dose administration aids – for example, Webster-paks®
- pre-packaged and labelled medicines, such as samples, trial packs or emergency prescription packs
- sig codes (short codes for data entry), which are used to improve efficiency and vary across hospital and community health services. They are not used on consumer-facing medicine-related information
- where and how the label is placed on the manufacturer's primary pack and/or secondary packaging.

The standards have not been specifically validated in CALD groups. Although the tools for clear presentation of medicines information apply, there is an opportunity for further research to support communicating about medicines to CALD communities.

Clear instructions for the consumer require detailed, unambiguous instructions from the prescriber, and inclusion of the instructions clearly and explicitly on the label. A detailed standard will help enable consistency, noting that this should align with other recommendations from the *Australian Pharmaceutical Formulary and Handbook* and the PBA.

2.2 Development of the standard

This standard was developed based on:

- Best practice for display of medicine-related information to consumers, and consumers' needs and preferences for medicine-related information (Appendix 1)
- Recommendations from a stakeholder roundtable[1] (Appendix 2)
- Data from qualitative user testing of prototype labels with consumers in Australia (Appendix 3)
- Data from quantitative evaluation of prototype labels in Australia (Appendix 4)
- Governance and legislative requirements (Section 3 and Appendix 5).

Development of the standard was informed by a research team with expertise in medicines information, graphic design and pharmacy; and the valuable contributions of many stakeholders (see Acknowledgements).

3 Governance of dispensed medicine labelling

Several requirements and professional standards specify the size and content of the label, to help provide consistent and standardised information to consumers.

3.1 Label size

Medicines packaging must dedicate a space of at least width 70 mm × height 30 mm for the dispensing label, according to the Therapeutic Goods Administration (TGA) Therapeutic Goods Order (TGO) 91.[31,32] This is a minimum size, and manufacturers are encouraged to follow best practice by leaving as large a space as possible for the dispensed medicine label. There are some exceptions in TGO 91 for label space allocation – for example, for small containers.

The dispensed medicine label size used by many pharmacy dispensing systems is currently width 80 mm × height 40 mm.

3.2 Label content

Legislative requirements for the content of dispensed medicine labels are defined in the poisons and therapeutic goods regulations in each state and territory. Pharmacists and other dispensing health professionals must comply with the regulations of the state or territory in which they practise.

Legislative requirements are generally reflected in guidelines such as the *Guidelines for Dispensing of Medicines* from the PBA (Appendix 5)[33] and the latest edition of the *Australian Pharmaceutical Formulary and Handbook* from the PSA.[28]

3.3 Additional legislative requirements

All labels must comply with relevant national and state and territory legislation and guidelines.

Pharmacists and other dispensing health professionals are responsible for ensuring compliance with all relevant legislation and professional guidelines in the state or territory in which they practise. Legislative requirements may differ between states and territories, and between community and hospital-dispensed medicine labels.

TGO 91 specifies requirements for labelling of proprietary medicines on the manufacturer's original medicine packaging. Although the principles in TGO 91 are relevant, the legislation does not apply to the content of dispensed medicine labels.

3.4 Active ingredient prescribing

Displaying the active ingredient name on the label is consistent with legislation for active ingredient prescribing.[34] Under this legislation, the prescriber must prescribe by active ingredient. The prescriber may also include the brand name of the medicine for clinical reasons and in consultation with the consumer. The *Active Ingredient Prescribing User Guide* describes principles for including the brand name on a prescription.[35] On dispensing, the brand name should be added to reflect the brand of medicine dispensed.

The legislation covers prescribing of medicines on the Pharmaceutical Benefits Scheme, but the principles apply to all medicines. Although the legislation does not cover dispensed medicine labelling, consideration should be given to consistent presentation of medicine-related information on both the prescription and the dispensed label.

3.5 Brand substitution

The dispensed medicine label should indicate when brand substitution has taken place, at least on the initial occasion. The PSA's *Professional Practice Standards* (version 5, 2017)[36] contains an action relating to brand substitution of medicines. A record must be made in the dispensing history or consumer's healthcare plan, and on the medicine label when initial brand substitution occurs (noting that brand substitution is not controlled in hospital settings). The consumer may find it helpful to continue including the brand name of the originator product (Standard 3).

3.6 Cautionary advisory labels

CALs are applied in addition to the dispensed label at the point of dispensing. They comprise ancillary labels (identified by numbers) and additional instructions (identified by letters).

Ancillary labels are recommended to be affixed to the manufacturer's primary pack and/or secondary packaging as a separate label. The colour and design are intended to draw the consumer's attention to the important information on the label. They provide an opportunity to engage with the consumer or their carer about the safe and effective use of the medicine.

Additional instructions provide information about the appropriate use and storage of medicines. Additional instructions may be affixed to the manufacturer's primary pack and/or secondary packaging. Alternatively, the words can be incorporated into the dispensing label. Pharmacists are advised to use professional judgement when deciding where to place these instructions.

Recommendations for use of CALs are described in the *Australian Pharmaceutical Formulary and Handbook*.[28] The wording and presentation of CALs are beyond the scope of this standard. However, there may be some benefit in reiterating CAL instructions on the label (Supporting strategy 3).

4 Standards for dispensed medicine labels

This *National Standard for Labelling Dispensed Medicines* includes the following standards for communicating medicine-related information. In addition to this standard, labels must also comply with relevant legislation and guidelines in each state and territory.

The standards for dispensed medicine labels are:

- Standard 1: Prominently display the information that consumers need to take their medicine safely and effectively
- Standard 2: Use a standardised format and order so that each element appears in the same place every time
- Standard 3: Signpost and display the active ingredient name first, followed by the brand name
- Standard 4: Include strength, as a quantity of active ingredient(s) with the relevant unit(s) of measure, after each active ingredient name. Use a clear statement of strength for liquid medicines
- Standard 5: Include the formulation in full
- Standard 6: Use numerals (digits) for dosage quantities, except for fractions
- Standard 7: Use explicit and clear dosing instructions
- Standard 8: Include the indication for use of the medicine, whenever possible, and considering consumer confidentiality
- Standard 9: Include the maximum dose, if relevant
- Standard 10: Express the pack size or quantity with units and place in a separate location from the strength
- Standard 11: Express discard-by information with a date, if possible
- Standard 12: Include a machine-readable verification code on the dispensed label to allow verification of the medicine during the dispensing process.

Standard 1: Prominently display the information that consumers need to take their medicine safely and effectively

Information on how to take the medicine safely and effectively is the most important information on the label and should be prominently displayed. This standard defines the information that consumers need to take their medicine safely and effectively as:

- Active ingredient name
- Brand name
- Strength (or concentration for liquid formulations)
- Formulation
- Explicit dosing instructions
- Consumer's name.

This information should appear first, so it has more prominence (Figure 1.1). It should be kept together and be displayed in as large a font as possible to maximise legibility.

Pre-printed information should be given less prominence (Figure 1.2).

Figure 1.1: Prominently display the information that consumers need to take their medicine safely and effectively

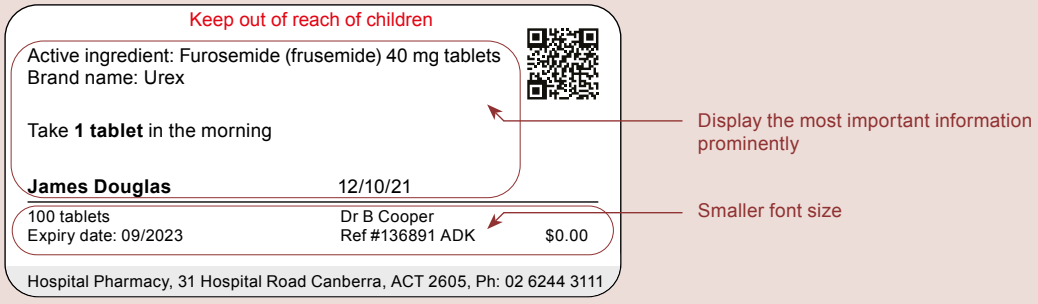
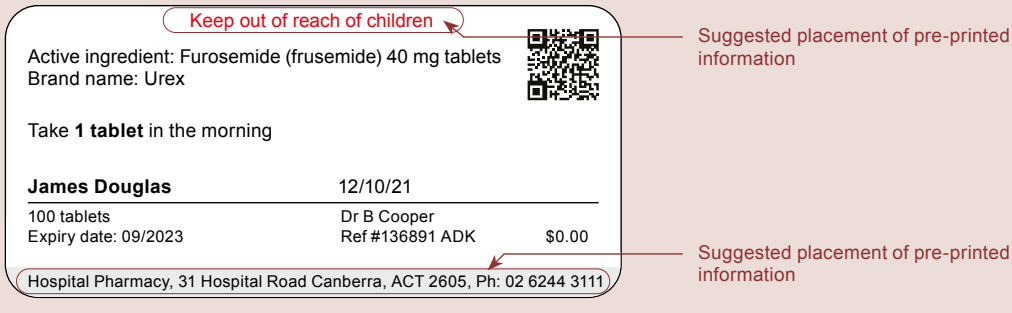


Figure 1.2: Suggested placement of pre-printed information



Rationale

This information is important because consumers need to know that they are taking the correct medicine (active ingredient, brand name, strength/concentration) in its correct form (formulation), in the correct way and at the correct times (dosing instructions), and that the medicine is intended for their use (consumer's name).

By organising the information in the way that best reflects how most consumers seek out and understand medicine instructions, consumers can locate the most important information on how and when to use the medicine quickly and easily. Maximising the space allocated to the most important information will also help with this.

Implementation

Some information that is legally required on the label is also part of the information that is important for the consumer to take their medicine safely and effectively. This includes the consumer's name, because consumers need to be sure that the medicine has been prescribed for them. Consider cultural naming conventions, the consumer's preferred name, and whether additional names are needed to assist identification.

Other required information that is not related to instructions for use should be given less prominence. This includes the pharmacy contact details, unique prescription number, prescriber name and date of dispensing. Information that does not relate to instructions for use should be positioned after the most important information outlined above, either towards the bottom of the label or in one column of a two-column format. This information may also be presented in a smaller font size than the most important information.

Font size could be used to reflect three tiers of information:

- Most important information (see above) – use largest font size possible and appropriate for the label size
- Other information that is consumer- and medicine-specific, such as prescriber, quantity, date of dispensing, provision for initials of the dispenser and pharmacist checking – use a smaller legible font size
- Pre-printed information, such as dispenser/pharmacy address and contact details, and 'Keep out of reach of children' – use a smaller legible font size.

Standard 2: Use a standardised format and order so that each element appears in the same place every time

Table 2.1 lists the elements of a label. The most important information for consumers (see Standard 1) should be presented in a standard and consistent order. See Table 2.1 and Figure 2.1.

Table 2.1: Standardised format and order for labels

Label element	Example	Status and source of label inclusion*	Notes
Active ingredient	Paracetamol	Mandatory (standard and legal)	Sentence case and signpost (Standard 3)
Strength	500 mg	Mandatory (standard and legal)	Display as quantity and a unit of measure (Standard 4)
Formulation	tablets	Mandatory (standard)	Write formulation in full ('tablets', not 'tabs') (Standard 5)
Brand name	Panamax	Mandatory (standard)	Sentence case and signpost (Standard 3)
Dosing instructions	Take **2 tablets** every 4 to 6 hours, when needed for knee pain	Mandatory (standard)	Dose quantity using numbers (not words) (Standard 6) Optional**:** Bold type Explicit dosing interval times using a narrow range (e.g. 4 to 6 hours) (Standard 7, Supporting strategy 2), supported by indication (Standard 8) and maximum dose (Standard 9) Specify the indication for use (Standard 8) Optional: Use a Universal Medication Schedule (UMS) table or other standardised way of communicating explicit instructions or dosing intervals (Supporting strategy 1)
Maximum daily dose	**Do not take more than 8 tablets in 24 hours**	Mandatory in some cases (standard)	Mandatory for some (e.g. paracetamol); optional for others (Standard 7, Standard 9) Optional: Bold type (Supporting strategy 6)
Cautionary advisory label (CAL) information	**Take with or soon after food**	Optional as text (on the dispensed medicine label)	Reiterate CAL information as part of the dispensed medicine label to support the dosing instructions Optional: Bold type (Supporting strategy 6)
Consumer name	James Douglas	Mandatory (legal)	
Date dispensed	12/10/2020	Mandatory (legal)	Keep separate from other dates (e.g. expiry date, discard date) to avoid confusion

continues

Table 2.1: *continued*

Label element	Example	Status and source of label inclusion*	Notes
Quantity supplied	100 tablets	Mandatory (legal)	Write formulation in full ('tablets', not 'tabs') (Standard 5)
Expiry	Expiry: 09/2023	Mandatory (legal) in some states and territories	Refer to Pharmacy Board of Australia guidelines for compounded medicinal products
Unique identifier	2651791/9/0	Mandatory (legal)	Prescription reference number, usually generated by dispensing software systems with some exceptions
Mandatory warning	Keep out of reach of children	Mandatory (legal)	May be additional legal requirements. For example, in NSW, this must be upper case and red font (KEEP OUT OF REACH OF CHILDREN)
Pharmacy details	Pharmacy name, address, phone number	Mandatory (legal)	
Prescription reference	Ref #136891 ADK	Optional	
Subsidised price	Pharmaceutical Benefits Scheme requirement	Mandatory (legal) in some states and territories	
Prescriber details	Prescriber name	Optional	
Number of repeats available	5	Optional	
Dispensing machine-readable verification code		Mandatory (standard)	Used to verify the medicine during the dispensing process (Standard 12)

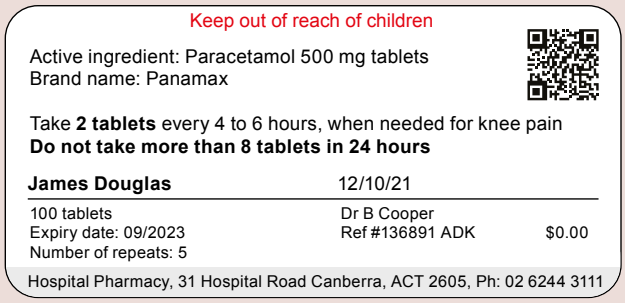
* The label element has a mandatory or optional status. This is qualified according to at least one source; this labelling standard and/or legislation.

Rationale

A consistent display format and order helps consumers find information and minimises the potential for confusion and misinterpretation (Table 2.1, Figure 2.1). Reducing variability in the way that medicine-related information is presented may help improve consumer understanding and health outcomes.

The standard order of information shown in Table 2.1 also ensures that information that is most important to the consumer is prominently displayed (see Standard 1).

Figure 2.1: Order of information on the label



Standard 3: Signpost and display the active ingredient name first, followed by the brand name

Present medicine names by:

- Listing the active ingredient name first, followed by the brand name
- Signposting both the active ingredient and brand names (that is, 'Active ingredient: XXX; Brand name: YYY')
- Using separate lines for the active ingredient name and the brand name.

Displaying the active ingredient name first on the label is consistent with legislation for active ingredient prescribing (see Section 3.4).[34]

The formulation should be stated after the active ingredient name (Standard 5). The formulation may be reiterated where it is part of a brand name.

Rationale

Signposting both the active ingredient name and the brand name optimises consumer understanding. It is a definitive confirmation of both names and is particularly helpful when they sound alike, or when the active ingredient is not noticeably technical- or chemical-sounding. Findings from user testing confirmed that displaying the active ingredient first is considered a change in practice by consumers, is less familiar to consumers and should be qualified by signposting (see Appendices 3 and 4).

Implementation

Where signposting is not possible – for example, due to space constraints – list the active ingredient name(s) first followed by the brand name in brackets. However, note that this approach is not superior to signposting and is not supported by the user testing findings.

The active ingredient may be made more prominent by using a larger font height than for the brand name (Supporting strategy 5). This is consistent with the move to active ingredient prescribing.

Active ingredient name

Display the active ingredient name as it appears in the Australian Medicines Terminology (AMT) or the International Nonproprietary Name (INN).

For products with multiple active ingredients, display the names in the same order as the ingredients on the manufacturer's packaging and the Australian Register of Therapeutic Goods (ARTG). If the order of ingredients in the AMT and the ARTG differ, use the order in the ARTG to ensure that the dispensed label and the packaging are consistent. The order of active ingredients on the manufacturer's packaging is reflected in the product entry in the ARTG. For generic products this order follows the order of active ingredients in the originator product.

Medicine ingredient names were updated in 2016 to align with INNs. A list of affected medicines describes the changes[37], some of which are minor. However, the change is substantial for some medicines, and medicine labels will need to use both active ingredient names until the end of the transition period (April 2023; except for adrenaline/epinephrine, which will be ongoing).

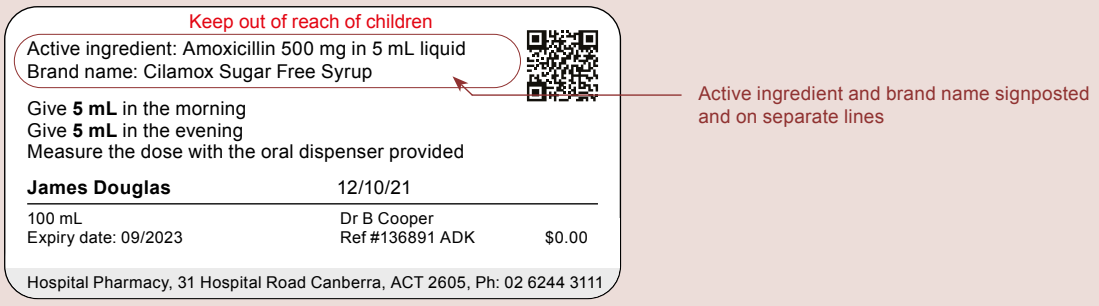
Brand name

Display the brand name as it appears in the ARTG using title case – for example, 'Cilamox Sugar Free Syrup'.

If generic substitution occurs, and in consultation with the consumer, include the brand name of the originator product if this has been used by the consumer previously, as it will help them to identify their medicine – for example, 'Brand: Pharmacor Amlodipine, same as Norvasc'.

Stating brand names as they appear on the ARTG will ensure that they are consistent with the product packaging. The brand name is useful for consumers when the brand name is more familiar to them than the active ingredient name, or when there are several active ingredients. The brand name should appear after the active ingredient name on a separate line, with signposting (Figure 3.1).

Figure 3.1: Signposting active ingredient and brand names

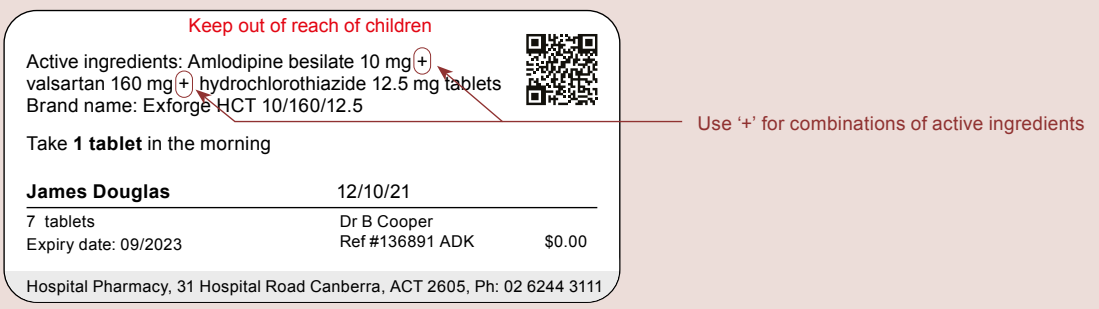


Medicines with two or three active ingredients

For medicines with two or three active ingredients, use a separator symbol such as '+' or '_' with a space between the symbol and the name – for example, 'perindopril arginine 10 mg + amlodipine 10 mg' (Figure 3.2). This is consistent with the *National Guidelines for On-Screen Display of Medicines Information*.[30] The medicines should appear in the order described in the ARTG so that the dispensed label and manufacturer's primary pack and/or secondary packaging are consistent.

Some medicines with two or three active ingredients may be better identified by the brand name, and these are described in the List of Excluded Medicinal Items issued to support active ingredient prescribing.[35]

Figure 3.2: Two or three active ingredients

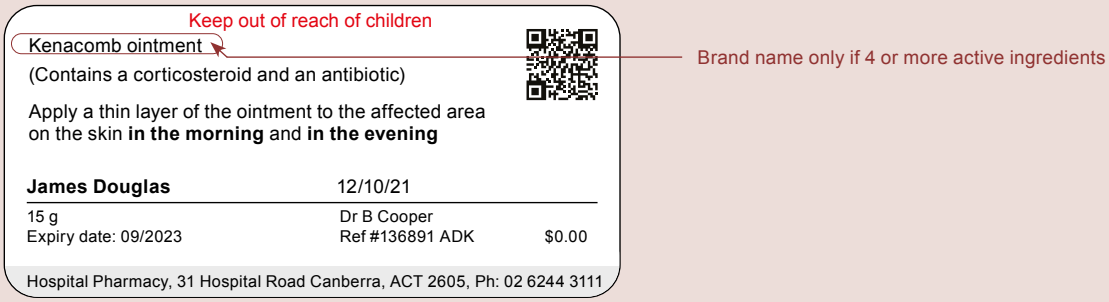


Medicines with four or more active ingredients

Display the brand name only for medicines with four or more active ingredients. Displaying many active ingredients makes it more difficult to identify the medicine, and prescribers and consumers may be more familiar with the brand name. This is consistent with active ingredient prescribing legislation[34] and the *National Guidelines for On-Screen Display of Medicines Information*.[30] However, prescribers and consumers still need to be aware of the importance of knowing and speaking about the active ingredients of medicines.

In Figure 3.3, Kenacomb is a combination of four active ingredients (nystatin, gramicidin, neomycin sulfate and triamcinolone acetonide) and is described by the brand name only.

Figure 3.3: Four or more active ingredients



Identifying active ingredients within products described by brand name only

Some medicines listed by the brand name may have an increased potential to cause harm if the active ingredient is not individually identified. In these instances, the active ingredient should be identified either individually or by class – for example, 'contains paracetamol', 'contains a corticosteroid medicine' or 'contains an antibiotic' (Figure 3.3).

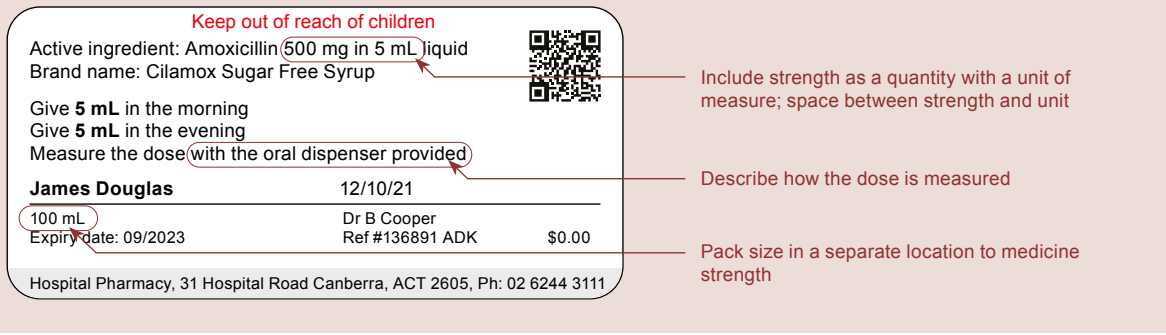
Standard 4: Include strength, as a quantity of active ingredient(s) with the relevant unit(s) of measure, after each active ingredient name. Use a clear statement of strength for liquid medicines

Include the strength, as a quantity with a unit of measure, after the active ingredient name – for example, 40 mg (Figure 4.1). Leave a space between the quantity and the unit. Write 'micrograms' in full (not 'mcg' or 'µg') and refer to the Commission's *Recommendations for Terminology, Abbreviations and Symbols Used in Medicines Documentation*.[38]

Figure 4.1: Strength as a quantity of active ingredient – for solid dose forms

For liquid dose forms, display the strength of the medicine as a clear statement – for example, '500 mg in 5 mL' (Figure 4.2). Avoid expressing strength as a percentage or as a concentration, such as '500 mg/5 mL'. An exception is for formulations that cannot be expressed without using a percentage – for example, 'Tobramycin 0.3% (w/v) eye drops' (Figure 7.4). Note the convention of no space between the number and percentage symbol.

Figure 4.2: Strength as a quantity of active ingredient – for liquids



For medicines with more than one active ingredient, the strength and relevant unit of measure should be stated directly after the active ingredient it refers to (Figure 4.3).

Figure 4.3: Strength as a quantity of active ingredient – for multiple active ingredients

Rationale

Descriptions of medicines contain structured combinations of words and numbers. The combination of a medicine name with its associated strength is an essential part of the medicine's identification.

The juxtaposition of two sets of numbers with different meanings can cause confusion. It is important to keep the medicine strength separated from other numbers that may appear on the dispensed label, such as quantity. This is assisted by using a consistent format and order (Standard 2).

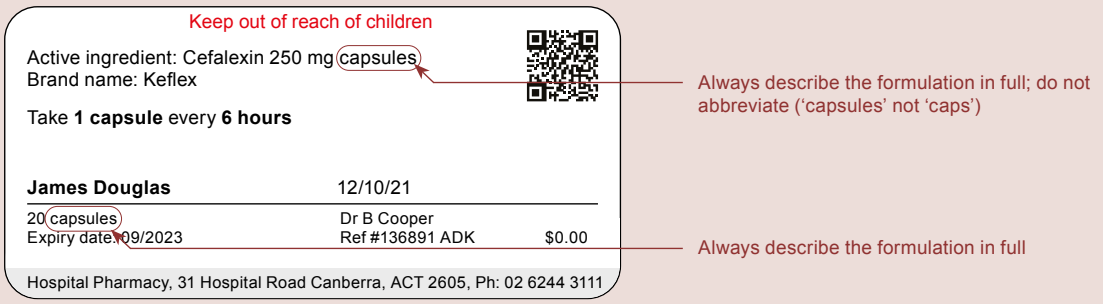
| Standard 5: Include the formulation in full

Include the formulation in full, with no abbreviations – for example, 'tablets', not 'tabs'.

Identify the formulation on the label after the active ingredient(s) and the strength, and as part of the pack size or quantity description if appropriate (Figure 5.1).

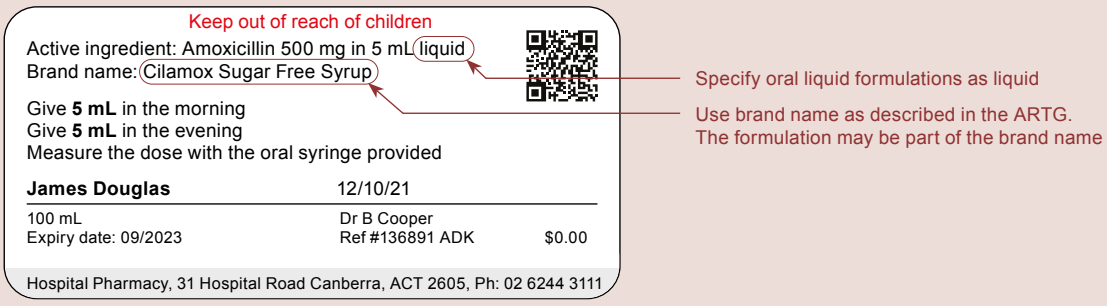
The formulation may also be specified as part of the brand name (Figure 5.2).

Figure 5.1: Solid formulations



Specifying oral liquid formulations as 'liquid' is preferred (Figure 5.2). Avoid terms such as 'suspension' that are less familiar to consumers and not used in everyday language. The exception is when these terms are included as part of the brand name listed on the ARTG.

Figure 5.2: Oral liquid formulations



Rationale

Technical terms are not well understood by consumers. Using plain language to express the formulation improves readability and comprehension by consumers.[6,30,39-43]

Avoid using abbreviations for the formulation.[30,39,41] The Commission's *Recommendations for Terminology, Abbreviations and Symbols Used in Medicines Documentation* details more standard full terms for dose formulations.[38]

Standard 6: Use numerals (digits) for dosage quantities, except for fractions

Display numerals, rather than words, for numerical dosage quantities – for example, 'Take 1 tablet', not 'Take one tablet' or 'Take ONE tablet'.

If an instruction includes a range, use a word between the numbers rather than a symbol – for example, '1 to 2' rather than '1-2' (which may be misinterpreted as 12).

Write fractions in words to prevent misreading numbers – for example, 'half', not '0.5' or '½', and 'quarter', not '0.25' or '¼' (Figure 6.1).

For small quantities of oral liquids, such as used in paediatrics, consider displaying the dose volume in numbers that relate to the markings on the oral dispenser – for example, '0.5 mL'.

Figure 6.1: Fractions in dosing instructions

Rationale

Numbers are more easily understood if presented as numerals (digits) rather than words. Consumer testing for the *National Guidelines for On-Screen Display of Medicines Information* also indicated that numerals were easier to understand than words when interpreting doses.[30]

However, fractions may be misinterpreted if displayed as numbers. For example, '½' may be read as 'half' or '1 or 2'. Decimal points may not be noticed, so '1.5' could be read as '15'.

User testing for this standard found that participants had mixed opinions on the use of numerals or words for conveying numbers. However, while there was some preference for numbers rather than words, there was no difference in consumers' ability to understand the information (see Appendices 3 and 4).

| Standard 7: Use explicit and clear dosing instructions

Clearly display the dose, frequency, duration and any other information that the consumer needs to take their medicine safely and effectively.

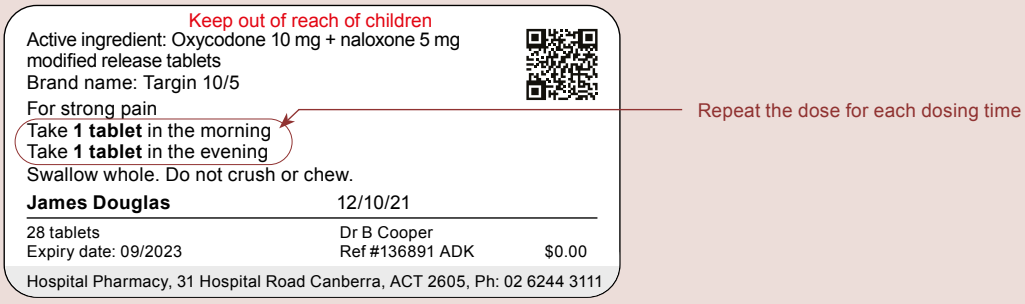
Dosing frequency

The dose and the timing of the dose should be linked together – for example, 'Take 1 tablet in the morning'. Studies in the United States[7,8,14] and Ireland[16] have shown that explicit instructions for dosing can improve consumer comprehension.

For dosing twice a day or more, repeat the dose for each dosing time to ensure clarity (Figure 7.1). For example:

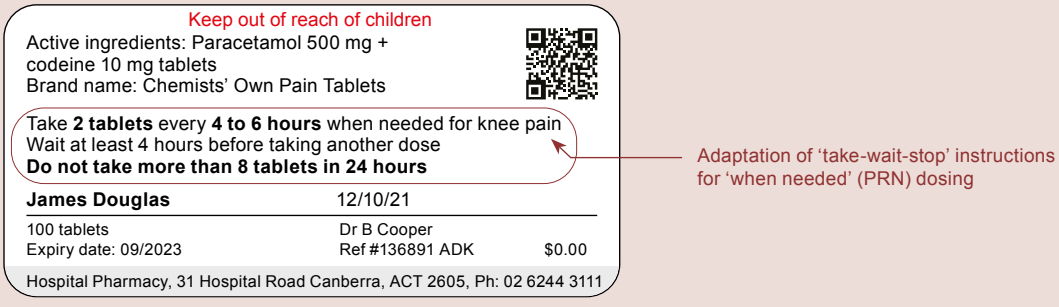
> Take **1 tablet** in the morning
> Take **1 tablet** in the evening
>
> NOT
>
> Take **1 tablet** in the morning and in the evening

Figure 7.1: Explicit and clear dosing instructions



For 'when needed' (PRN) medicines, the maximum dose must be stated clearly. The 'take-wait-stop' strategy is one method of explicitly stating PRN dosing instructions.[44] Figure 7.2 demonstrates an adaptation of this strategy.

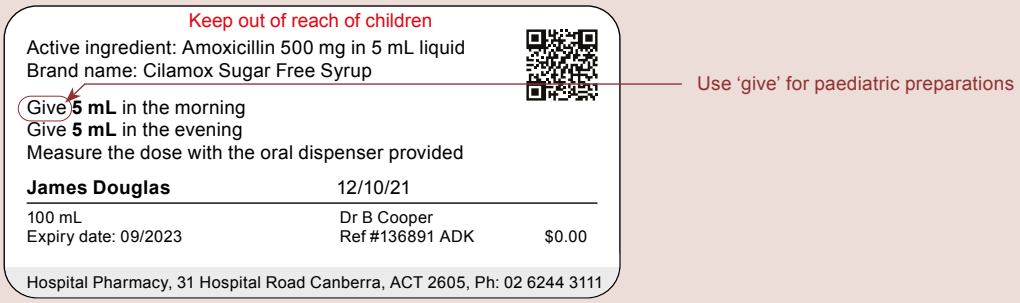
Figure 7.2: Explicit and clear dosing instructions



Administration to a child

Ensure the wording is appropriate for the consumer. For example, parents or carers of children would be expected to 'give' a dose rather than 'take' a dose (Figure 7.3).

Figure 7.3: Instructions for administering a medicine to a child

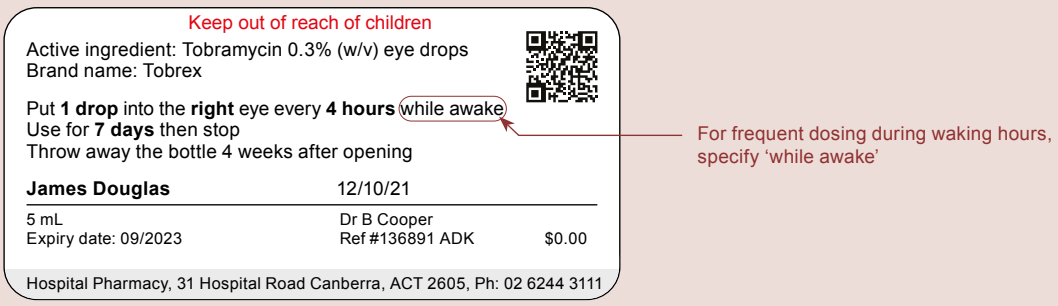


Describe how the oral liquid dose is measured – for example, 'with an oral dispenser'.[45]

Frequent dosing

For frequent dosing described in hours, provide the total number of doses in 24 hours, if possible, to prevent overdosing. If dosing is frequent but only required during waking hours, qualify the dosing frequency as 'while awake' (Figure 7.4).

Figure 7.4: Frequent dosing during waking hours



Use easy to understand language

Technical terms and jargon are not well understood by consumers. Using common, everyday words improves readability and comprehension by consumers. For example, use ‘inside the cheek’ instead of ‘buccal’, ‘under the tongue’ instead of ‘sublingual’, or ‘place’ or ‘put’ instead of ‘instil’, and apply to the affected area’ instead of ‘topical application’.

Complex dose instructions

Consumers need clear instructions for taking non-oral dosage forms and oral dosage forms with complex dosing instructions – for example, non-daily dosing, weaning schedules and variable doses.

This is beyond the scope of this standard; however, individual health service organisations have developed guidance on dispensed labels for non-oral dose forms and more complex instructions. These may not all draw from established best-practice principles or be supported by the available evidence. Further work based on the evidence-based standards and supporting strategies within this document, and broader available literature, is needed to make recommendations in these areas.

Standard 8: Include the indication for use of the medicine, whenever possible, and considering consumer confidentiality

The indication or purpose for which the medicine has been prescribed should be included on the dispensed label:

- To qualify the reason for taking 'when needed' (PRN) medicines – for example, 'when needed for pain' (Figure 8.1), or
- When the indication is specified by or agreed with the prescriber, and if the dispensing clinician is certain of the indication. The indication on the label should be consistent with any indication on the prescription.

Care must be taken when including the indication so that the prescriber's intention is reiterated and not contradicted.

Express the indication in plain and simple language that the consumer can understand easily – for example, 'to help lower blood pressure' not 'for hypertension'; and, for furosemide, 'to reduce fluid' may be better understood than 'for heart failure'.

Describe what the medicine does to relieve or control the indication – for example, 'to help control blood sugar' rather than 'for diabetes'. It could be appropriate to use the word 'diabetes', but only if the dispensing clinician is certain that this is how the consumer understands their medicine.

Figure 8.1: Indication or reason for taking the medicine

Rationale

Previous qualitative research has identified circumstances where stating the indication on the label may be beneficial.[46,47] Including the indication on the dispensed medicine label can help consumers understand their medicines and may assist caregivers who may be involved with managing medicines for others. Including the indication may be particularly helpful for consumers (and their carers) who are taking multiple medicines or starting a new medicine that is unfamiliar to them.

Including the indication on the dispensed medicine label may assist in the relay of clinical information at transfer of care between healthcare settings.

Consumer confidentiality should be considered where the indication is not already part of the prescriber's specified instructions for use. Printing the consumer's name alongside the indication could pose issues of privacy in relation to diagnosis. Consumers should agree that specifying the indication is appropriate to them and is for their benefit. This can be determined through conversation with the consumer.

Many medicines have multiple indications for use, and some medicines can be prescribed for off-label indications. The dispensing clinician must be certain of the indication for which the medicine has been prescribed to avoid error and consumer confusion.

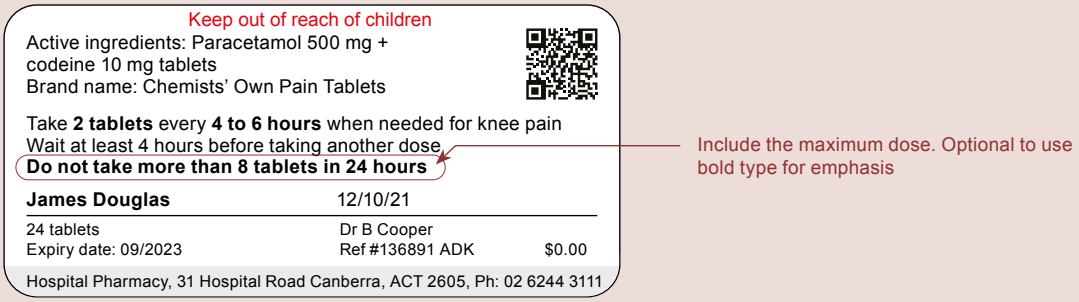
| Standard 9: Include the maximum dose, if relevant

Include the maximum dose of medicine on the label (Figures 9.1 and 9.2) when:

- The prescriber has indicated a maximum dose on the prescription
- The maximum dose is less than what the consumer would take if they followed the dosing frequency on the label
- The maximum dose is well established, such as for paracetamol or tramadol
- The medicine is prescribed 'when needed' (PRN); for PRN medicines, see Standard 7. Also include the phrase 'when needed' immediately after the dose frequency (Figure 8.1).

State the number of tablets or volume of oral liquid – for example, '**Do not take more than 8 tablets in 24 hours**', '**No more than 40 mL in 24 hours**' (Figures 9.1 and 9.2).

Figure 9.1: Maximum daily dose



Consumer testing for the *National Guidelines for On-Screen Display of Medicines Information* indicated that maximum daily doses can be a source of confusion, especially for oral liquids. For oral liquids, doses may also be specified in brackets – for example, '**Do not take more than 40 mL (4 doses) in 24 hours**' (Figure 9.2).

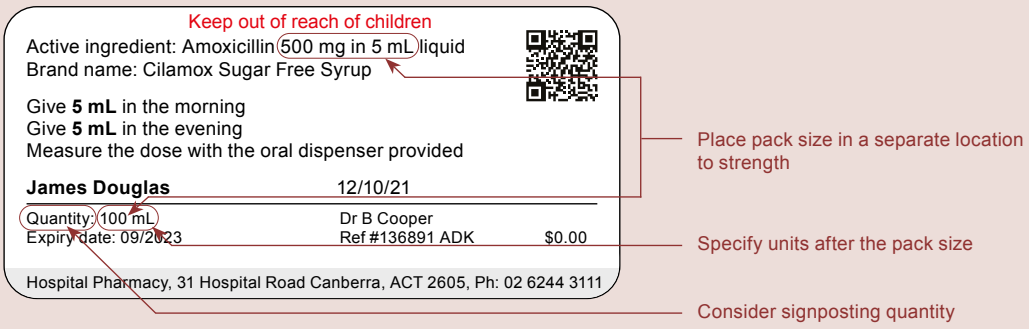
Figure 9.2: Maximum daily dose for oral liquid formulations

Standard 10: Express the pack size or quantity with units and place in a separate location from the strength

When expressing pack size or pack quantity supplied, specify the units immediately after – for example, '100 capsules', not '100'.

Place the pack size details in a separate location to the strength (Figure 10.1) to reduce the likelihood of confusion. Also consider signposting – for example, 'Quantity: 30 tablets'.

Figure 10.1: Pack size

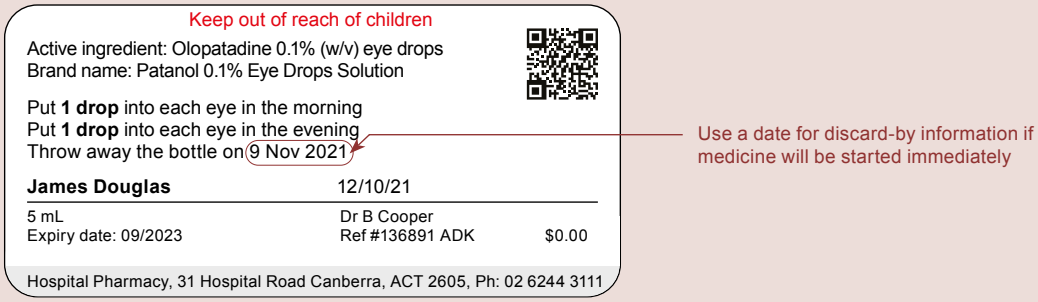


Standard 11: Express discard-by information with a date, if possible

For most medicines, the expiry will reflect the manufacturer's expiry date. However, for some dispensed medicines, the expiry will differ from the manufacturer's date. This includes where medicines are reconstituted and have a related expiry, and where medicines must be discarded within a limited period after opening. Note that a CAL is available with a space to annotate the date the container was opened.

For medicines that will be started immediately, clearly state when the dispensed medicine expires by expressing discard-by information using an exact date – for example, 'Throw away on 24 Nov 2021' (Figure 11.1).

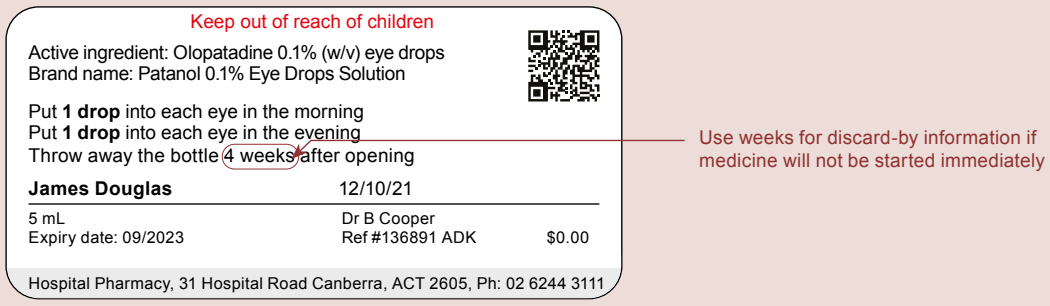
Figure 11.1: Discard-by date



For medicines that may not be started immediately, express the discard-by information:

- In weeks rather than days, if the duration is more than 1 week – for example, 4 weeks rather than 28 days (Figure 11.2), or
- In months rather than weeks if the duration is more than 1 month.

Figure 11.2: Discard-by information in weeks



Use familiar language to convey this information. For example, 'throw away' is a more familiar term than 'discard'. Also, describe what should be thrown away (such as the whole bottle or the prepared solution). The consumer should be encouraged to discard or throw away by returning the item to the pharmacy for disposal.

Rationale

Using a date is preferable to providing a time period (such as 'in 4 weeks') so consumers do not need to calculate the discard-by date. It is also more appropriate for medicines that expire in fractions of weeks (such as 3 or 10 days) or in longer time frames (such as 6 months).

User testing for this standard suggested that there was no difference in participants' ability to determine when the medicine should be discarded, whether the throw away/discard-by date was in days or weeks.[48] However, participants reported in qualitative interviews that weeks are easier to comprehend than days.[48]

Implementation

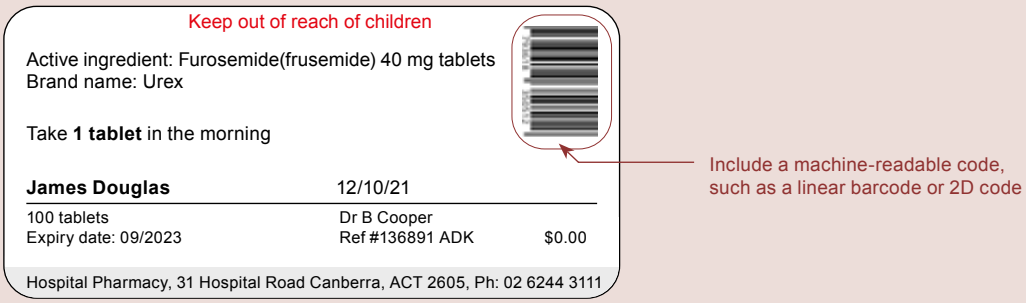
This deviation to existing practice is acknowledged and was taken into consideration as part of the standard's consultation process.

Standard 12: Include a machine-readable verification code on the dispensed label to allow verification of the medicine during the dispensing process

Include a machine-readable verification code, such as a two-dimensional code or linear barcode, on the dispensed label to allow verification of the medicine during the dispensing process. The machine-readable verification code should take up as little space on the label as possible, with enough resolution for accurate scanning.

Examples of two-dimensional codes are found throughout this standard. An example of a linear barcode is shown in Figure 12.1.

Figure 12.1: Machine-readable verification code



Rationale

The machine-readable verification code on the label is designed to prevent dispensing errors. Machine-readable verification has been associated with a significant reduction in dispensing errors, and is an important part of product checking and verification during the dispensing process.[49]

The machine-readable verification code on the label is different to the machine-readable code on the manufacturer's packaging, which includes information about the manufacturer and is used for selection and traceability. These two codes are cross-checked during dispensing to prevent selection errors.

Proprietary machine-readable verification codes may also be generated for consumers to identify their medicine and reorder medicines through mobile applications, allowing better consumer management of, and control over, their medicines. These machine-readable verification codes should be readily identifiable by consumers and placed separately to distinguish them from the machine-readable verification codes on the dispensed label and primary manufacturer's pack.

5 Supporting strategies for dispensed medicine labels

The following supporting strategies are based on the evidence in the literature on principles of good information design and writing. The supporting strategies are not a mandatory part of this standard, but are optional actions to further improve clarity for consumers.

Supporting strategies for dispensed medicine labels are:

- Supporting strategy 1: Tabulate or list the dosage and frequency for medicines with complex dose schedules
- Supporting strategy 2: Specify the dosing interval using a narrow range or explicit dose times
- Supporting strategy 3: Include essential instructions from cautionary advisory labels
- Supporting strategy 4: Use a standard sans serif font
- Supporting strategy 5: Use a minimum font height of 4 mm for all text on the label
- Supporting strategy 6: Use bold type for emphasis
- Supporting strategy 7: Use sentence case for all label text unless otherwise required by legislation
- Supporting strategy 8: Use a minimum label size of width 80 mm × height 40 mm
- Supporting strategy 9: Use transparent flag labels for smaller containers.

Supporting strategy 1: Tabulate or list the dosage and frequency for medicines with complex dose schedules

Use a Universal Medication Schedule (UMS) or other standardised way of communicating explicit instructions or dosing intervals.[40]

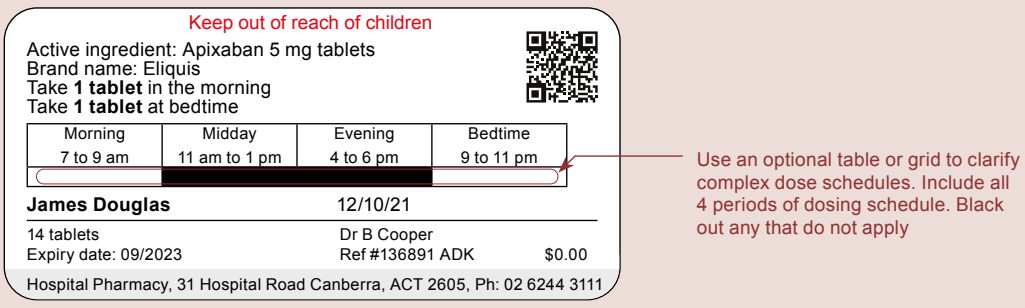
For consumers with complex medication needs, specifying doses in a table can help to clarify which medicines should be taken at which times. In the table or grid:

- Include all four time periods in the table or grid to ensure consistency in the use of a UMS across labels for different dosing frequencies
- Indicate any periods that do not apply by blacking them out, rather than leaving them blank
- Follow the time periods
  - morning (7 to 9 am)
  - midday (11 am to 1 pm)
  - evening (4 to 6 pm)
  - bedtime (9 to 11 pm).

Rationale

A UMS or standardised way of communicating explicit instructions or dosing intervals has been advocated for medicine labels.[40] Integrating a table format or grid into a label is one way to complement the written instructions on the label.[15] A table format can help to visually convey dosing instructions that are expressed using a UMS format – for example, morning, midday, evening, bedtime (Figure SS1.1).

Figure SS1.1: Universal Medication Schedule table to clarify dosing and frequency



A list format may be used instead of a table (Figure SS1.2).

Figure SS1.2: List for dosing instructions

Specific time frames – for example, 7 to 9 am in relation to morning – mapped to each of the four UMS time periods (morning, midday, evening, and bedtime) may also be helpful for consumers. However, consider the appropriateness of the specified times with regard to the consumer's lifestyle and routine – for example, shift workers.

Visual dosing guides can be helpful for consumers who have complex medicine regimens or low health literacy. Evidence supports tabulation for medicines that are administered more than once a day.

Supporting strategy 2: Specify the dosing interval using a narrow range or explicit dose times

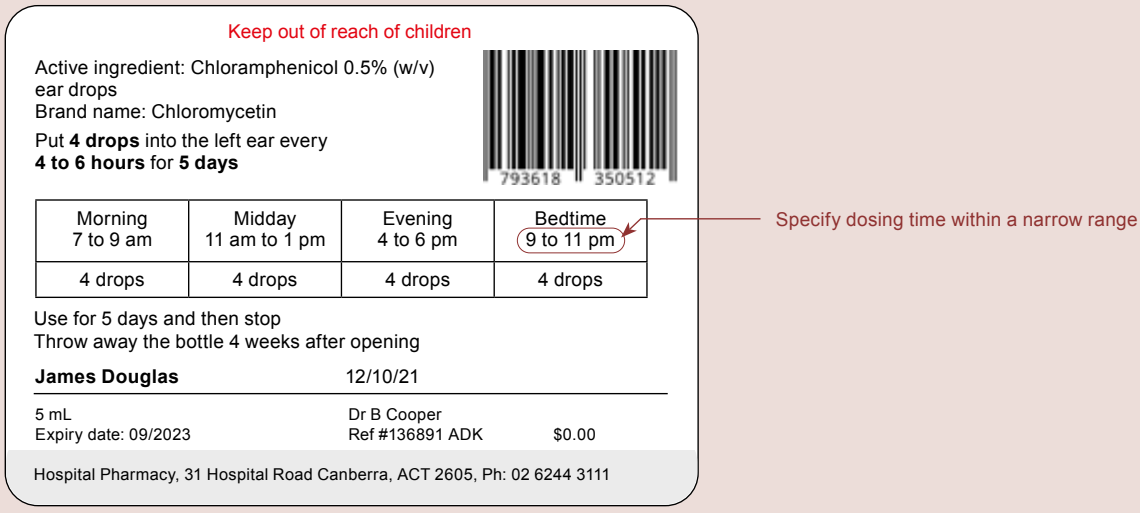
In some cases, it may be appropriate to provide dosing instructions that explicitly convey the dosing interval in hours and/or specify time frame(s) when medication dose(s) should be taken.

Clearly state the specific dosing interval using a narrow range that incorporates some flexibility when appropriate – for example, 4 to 6 hours, rather than 6 hours (Figure SS2.1). The inclusion of indication for use and/or the maximum dose according to Standards 8 and 9, respectively, will support understanding of the narrow dose range. Counselling should emphasise that the time periods are a guide and that the dose is to be taken somewhere within this window.

Only include a specific dosing interval (for example, 6 hours) if this level of specificity is critical to the dosing regimen.

There are many opportunities to establish appropriate time frames for medicine administration with the consumer. These include at prescribing, dispensing, counselling and all other medicine-related services delivered by health professionals, including when conducting a medicines-use review.

Figure SS2.1: Universal Medication Schedule table with explicit dosing times



Supporting strategy 3: Include essential instructions from cautionary advisory labels

If the information on a CAL forms an essential part of the dosing instructions, then this information should be included as a CAL or as part of the dispensed medicine label, noting that CALs may be overlooked by consumers.[50] This information should only be included on the label if there is sufficient space to avoid overcrowding and maintain legibility.

CALs with information that may form an essential part of dosing instructions include:

- Swallow whole. Do not crush or chew
- Take with or soon after food
- Take at least half an hour before food
- Take immediately before food
- Shake well before each use.

Rationale

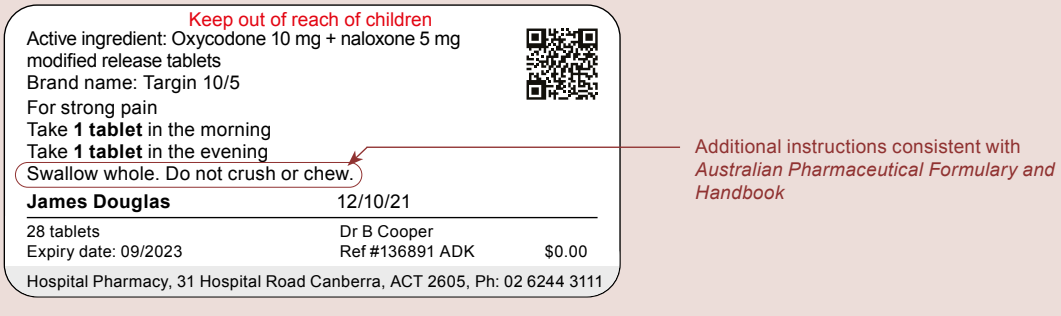
Mandatory warning labels listed in the Standard for the Uniform Scheduling of Medicines and Poisons[29] and the wording and use of CALs in accordance with guidance in the *Australian Pharmaceutical Formulary and Handbook*[28] are outside the scope of this standard.

The *Australian Pharmaceutical Formulary and Handbook* recommends pharmacists exercise professional judgement to determine whether to include certain dosing instructions for an individual consumer.[28] For example, some medicines should be taken with or soon after food because efficacy of the medicine is compromised if the medicine is taken on an empty stomach, but some medicines should be taken with or soon after food to minimise adverse effects. The pharmacist, in consultation with the consumer, will tailor advice about administration to maximise adherence.

Where CALs may be overlooked and may not be perceived to be part of the primary instructions, the pharmacist may reiterate the essential dosing instruction.

Ensure any additional information included on the medicine label is consistent with that in the *Australian Pharmaceutical Formulary and Handbook*[28] and the CALs (Figure SS3.1). Wording variations are permitted provided the meaning is preserved.

Figure SS3.1: Essential dosing instructions from a cautionary advisory label



Supporting strategy 4: Use a standard sans serif font

Choose a clear, easy-to-read sans serif font, such as Arial. Do not expand or condense the font, and ensure that it is easy to read in its regular, bold and italic forms.

Font choice affects readability. A font that is difficult to read or unclear in any way can make it difficult for consumers to understand the information and take their medicine safely and effectively.[51,52]

Supporting strategy 5: Use a minimum font height of 4 mm for all text on the label

The Standard for the Uniform Scheduling of Medicines and Poisons[29] specifies a minimum font size of 1.5 mm. It is recommended that, for dispensed medicine labels, a minimum font size of 12 point is used. This equates to a text font height of approximately 4.2 mm. Note that common sans serif fonts differ slightly in height, with 'Calibri 12 point' being smaller than 'Arial 12 point'.

Rationale

Larger font size improves legibility and may be used for emphasis. The most important information (see Standard 1) should appear in as large a font as possible to maximise legibility and ensure that the most important information is displayed prominently. If space allows, the font size can be further increased at the dispensing clinician's discretion.

A larger font size could be used for the active ingredient name. However, care should be taken to avoid too many different font sizes. This can be counterproductive. Different font sizes for certain words will affect the line spacing above and below and could make the label look haphazard.

This standard encourages the use of three tiers of font sizing to reflect the three tiers of information importance and prominence (Standard 1). It is important to retain enough white space on the label to maintain legibility and prevent overcrowding of information.

| Supporting strategy 6: Use bold type for emphasis

Bolding for emphasis is advocated as part of best-practice information design and writing principles (see Table A1.1 in Appendix 1).[51] However, overuse of bold type can reduce its impact. Pharmacists and other dispensing health professionals should use their judgement to ensure that only appropriate elements are in bold (Figures SS6.1 and SS6.2).

Examples of terms, words and phrases that could be in bold include:

- Dose – for example, 'Take **1 tablet**'; 'Give **1 mL**'
- Fractions – for example, '**half**' or '**quarter**'
- Dosing interval – for example, 'every **4 to 6 hours**'
- Maximum daily dose, if applicable – for example, '**Do not take more than 8 capsules in 24 hours**'
- Essential dosing instructions – for example, '**Take with or soon after food**'.

Figure SS6.1: Bold type for emphasis

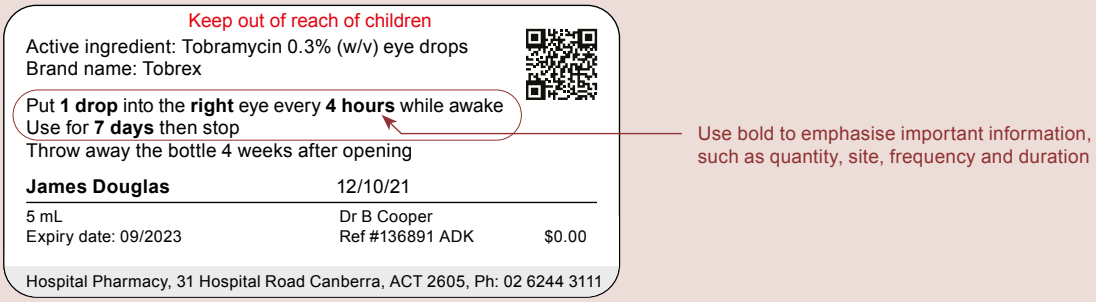
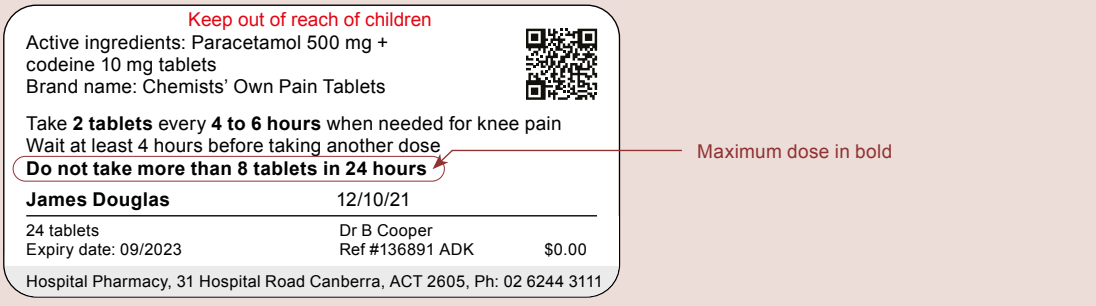


Figure SS6.2: Bold type for maximum dose



Supporting strategy 7: Use sentence case for all label text unless otherwise required by legislation

Use sentence case for most of the text on the label, including the signposting, the active ingredient and the instructions.

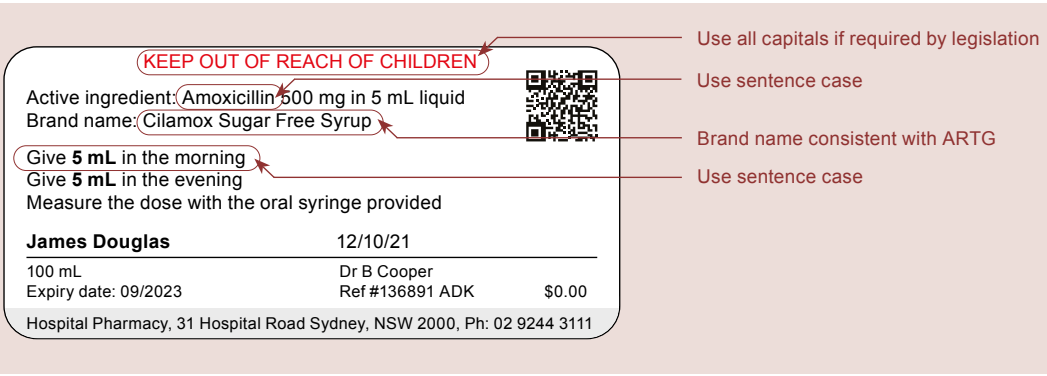
Only use capital letters for the first letter of:

- The first word of each sentence
- The first word of the active ingredient(s)
- Each word of the brand name as it appears in the ARTG – for example, 'Cilamox Sugar Free Syrup'
- Other proper nouns, such as consumer name, prescriber name and pharmacy address.

Sentence case is easier to read than full capitalisation. The shape of whole words assists in reading. Lower-case letters have a larger number of unique shapes than capital letters. This creates greater variation in letter appearance and less confusion when words are read. Text written in all capitals is read more slowly and less accurately than text in lower case.

This supporting strategy also applies to statements such as 'Keep out of reach of children' or 'Prescription only medicine'. However, some legislation requires presentation of these statements in title case or all upper case – for example, in New South Wales (Figure SS7.1).

Figure SS7.1: Sentence case for most label text



Do not use all capital letters for any part of the label unless required by legislation.

Tall Man lettering may be used within the active ingredient and brand names according to the National Tall Man Lettering List.[53] Tall Man lettering is a tool for clinicians to help reduce the risk of selection errors with look-alike, sound-alike medicine names. Therefore, it does not need to be introduced into the dispensed label. However, if Tall Man lettering flows from prescribing to the dispensed label, consumer testing indicates this is acceptable to consumers.[30]

Supporting strategy 8: Use a minimum label size of width 80 mm × height 40 mm

While use of a minimum label size is recommended, increasing the label size to 90 mm × 65 mm:

- Increases the amount of space available to provide explicit instructions to the consumer
- Allows for the use of a larger standard font size
- Allows for inclusion of complex dose instructions when required
- Allows for the inclusion of a table.

If necessary, transparent flag labels should be used to avoid obscuring information on the manufacturer's pack (see Supporting strategy 9).

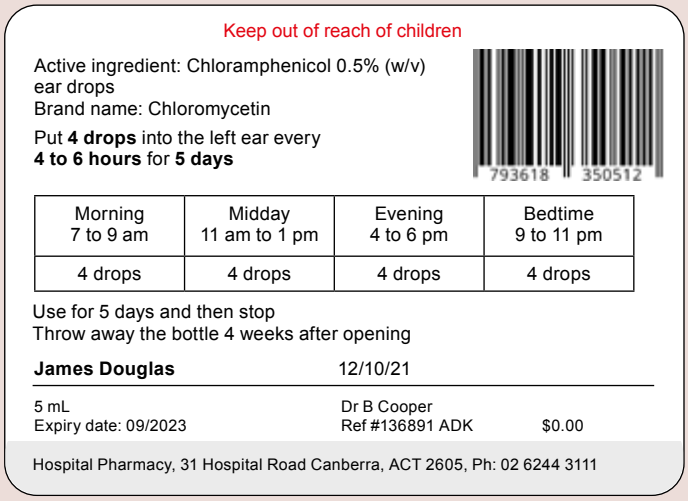
Rationale

Most pharmacy dispensing systems use labels measuring 80 mm × 40 mm.[32] A larger label of 90 mm × 65 mm can also be produced using the standard label printers that are found in most Australian pharmacies (Figure SS8.1).

TGO 91 specifies that medicine manufacturers must leave a minimum space of 70 mm × 30 mm for the dispensing label. However, guidance from the TGA on TGO 91 acknowledges the frequent use of an 80 mm × 40 mm label.

The dispensed label should not obscure information on the manufacturer's packaging, so manufacturers are encouraged to allocate space accordingly.

Figure SS8.1: Larger size dispensed medicine label



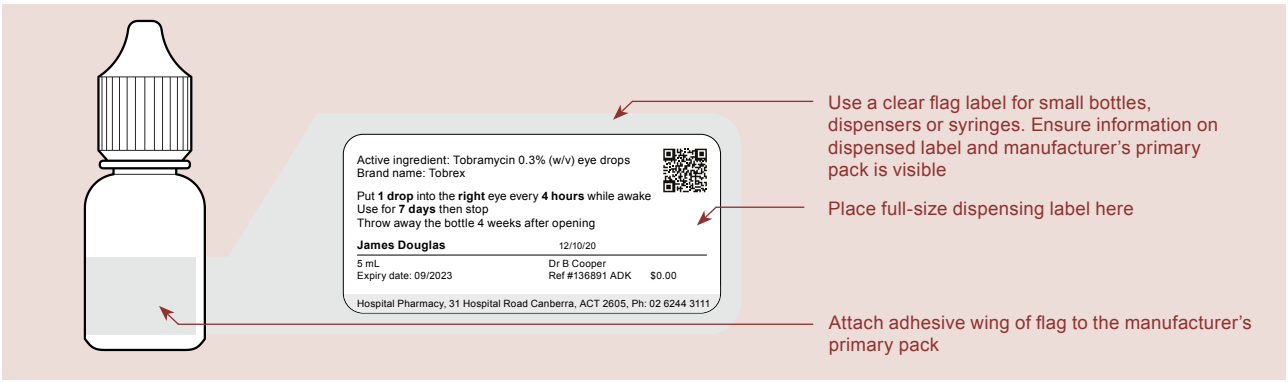
Supporting strategy 9: Use transparent flag labels for smaller containers

For small containers (such as eye drops), use a transparent flag label adhered to a full-size standard dispensing label. Using a flag label:

- Avoids the need to cut or fold the label
- Ensures that all label information on both the dispensed label and the manufacturer's label remains visible
- Allows the dispensed label to be applied directly to, and remain with, the manufacturer's primary pack.

The transparent adhesive wing of the flag label is attached to the container (Figure SS9.1). The flag label should not hinder use of the product.

Figure SS9.1: Transparent flag label for small containers



Rationale

Avoid folding the dispensed medicine label in half. Labels that are folded in half and attached to a small container are difficult to read and can easily be torn off the medicine container. Using a transparent flag label keeps the label flat and maintains readability for consumers.

The active ingredient name(s) and strength(s) on the manufacturer's packaging should not be obscured. This is especially important for medicines with four or more active ingredients if these do not appear on the dispensed medicine label.

6 Implementation of the standard

The standard is expected to benefit consumers and add value to the health system. The Commission is responsible for maintaining the standard and reducing barriers to its implementation.

Potential limitations relating to implementation of the standard that have been identified by stakeholders to date include:

- The need for education and awareness raising among pharmacists, other dispensing health professionals, regulators and software providers; and also, among consumers
- The amount of information required to comply with the standard, which may affect the size of the label
- The need to integrate these standards with other related standards, such as the Commission's *National Guidelines for On-Screen Display of Medicines Information*[30] and *Recommendations for Terminology, Abbreviations and Symbols Used in Medicines Documentation*[38]
- The need to ensure consistency of this standard with existing regulations
- Areas not covered by user testing for this standard, such as small containers, complex dose regimens or very long instructions, compounded medicines (noting the legal requirement to include all ingredients, including excipients, on the label), long medicine names, dose administration aids, and labelling for visually impaired consumers
- The need to engage with medical and pharmacy software providers to assess dispensing software limitations and modification of software systems to accommodate the standard
- The need to establish a governance structure for implementing standards and supporting strategies on a national scale.

The Commission will continue to work through implementation issues as a separate piece of work from this standard. An implementation plan and issues register will be developed to capture any issues not addressed by this standard.

Acknowledgements

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- Australian Dental Association
- Australian Digital Health Agency
- Australian Government Department of Health
- Australian Medical Association
- Canberra Health Services Pharmacy Department
- Children's Healthcare Australasia
- Consumers Health Forum of Australia
- Council of Australian Therapeutic Advisory Groups
- GS1 Australia
- Medical Software Industry Association
- Medicines Australia
- NPS MedicineWise
- Optometry Australia
- PDL (Pharmaceutical Defence Limited)
- Peter MacCallum Cancer Centre Pharmacy Department, Melbourne
- Pharmaceutical Society of Australia
- Pharmacy Board of Australia
- Pharmacy Guild of Australia
- Royal Australian College of General Practitioners
- Royal Melbourne Hospital Pharmacy Department
- Sir Charles Gairdner Hospital, Perth
- Society of Hospital Pharmacists of Australia
- State and territory representatives
- The University of Sydney School of Pharmacy
- Therapeutic Goods Administration
- Top End Health Service, Darwin.

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- Ms Jackie Crofton, Royal Darwin Hospital, Darwin
- Dr Alice Gilbert, Royal Darwin Hospital, Darwin
- Professor DK Raynor, School of Healthcare, The University of Leeds, United Kingdom
- Ms Shrada Chitlangia, School of Pharmacy, University of Nottingham, United Kingdom
- Ms Wing Poon, School of Pharmacy, University of Nottingham, United Kingdom
- Mr Brian Parkinson, Making Sense, Sheffield, United Kingdom
- Mr Daniel Lalor, Canberra Hospital, Canberra
- Mr Andrew Sobey, Canberra Hospital, Canberra
- Ms Kathryn Owers, Canberra Hospital, Canberra
- Ms Joanne Young, The Royal Melbourne Hospital, Melbourne
- Ms Sarah Charles, The Royal Melbourne Hospital, Melbourne
- Associate Professor Bhavini Patel, Top End Health Service, Darwin
- Ms Diana Shipp, Australian Commission on Safety and Quality in Health Care, Sydney.

The full qualitative and quantitative study reports list all contributors in each research area.

Appendix 1 Best practice for display of medicine-related information to consumers

Design, content and wording form the foundations of written medicine-related information. Guidance documents that support the development of well-written medicine-related information draw on principles of good information design and evidence from the literature (Table A1.1) and are relevant to dispensed medicine labels. Several literature reviews have summarised key evidence-based principles that drive good information design relevant to written medicine-related information.[6,54,55]

Table A1.1 provides a broad overview of relevant guidance and key findings from the literature that apply to development of dispensed medicine labelling that is easily understood by consumers. This national standard builds on this existing best practice and on evidence-based principles.

Importantly, each individual principle is not standalone – they are interdependent. Evidence-based principles and information design factors applied in combination support an effective dispensed medicine label that is fit for purpose.[55] Moreover, best practice also incorporates a multimodal approach where written communication is supported verbally. Evidence-based practice also relies on usability evaluations undertaken with the populations of interest to ensure that dispensed medicine labels have applied these principles to enable safe and effective medicine use.

Table A1.1: Summary of information design guidance and evidence base to support development of dispensed medicine labels

Label elements	Evidence to support label design (guidance documents and literature reviews)	Corresponding standard or supporting strategy
Content structure	Prominently display key medicine-related information[39,40,51]	Standard 1
	Include the consumer's name, medicine name (active ingredient and brand name), medicine strength, and instructions for use at the top of the label[39,40]	Standard 2 Standard 10 Supporting strategy 1
	Separate important and less important information on the label; in particular, separate instructions for use from less important information[39-41]	
	Group content appropriately[6,39-43,54,55]	
	Use a consistent and standardised format[30,39]	
	Use tables or visual aids to present certain information (e.g. instructions for use)[40,43]	
	Use bullet points[42,43,55] or lists of information[6,41]	
	Include each distinct dosing step in the instructions for use on a separate line[39,55]	

continues

Table A1.1: *continued*

Label elements	Evidence to support label design (guidance documents and literature reviews)	Corresponding standard or supporting strategy
Language and numbers	Use plain language and avoid jargon[6,30,39-43] Avoid using abbreviations[30,39,41] (exception: use approved abbreviations for quantities, such as mg or mL[38]) Use numbers rather than words for dose instructions[39-41,55], except for fractions[30] Include a space between letters/words and numbers – for example[30,41]: • between active ingredient / brand name and medicine strength • between numeric quantity and its associated unit, such as medicine strength	Standard 4 Standard 5 Standard 6 Standard 7 Standard 11
Specific information to include	Specify the indication for the medicine if appropriate[39-41] State both the active ingredient and the brand name on the label[30,41] Include warning information on the label (e.g. maximum daily dose specifying number of tablets or volume of liquid)[30] Communicate instructions for use clearly and explicitly (e.g. times of day such as morning, bedtime to be used to communicate instructions for use).[30,39-41,54,55] Avoid ambiguous instructions such as 'Take as directed by your doctor'[39] Express time using the 12-hour clock with a description of the broad time of day – for example, '9:00 in the morning'[30] State the dosing interval if evenly spaced doses are needed[30]	Standard 3 Standard 7 Standard 8 Standard 9 Supporting strategy 1 Supporting strategy 2 Supporting strategy 3
Typography and formatting	Use a larger font size if possible[6,39-42,51,55,56] Use a sans serif font[40,41,55,56] Use sentence case[39,55] Avoid all upper case[39-43,51,55,56] Use bold to emphasise selected words[39-43,51,55,56] Use appropriate white space[6,39,41,42,55] Use appropriate spacing, such as between letters or lines[39,41,42,56] Use left-aligned text[42,51,56] Use horizontal text[39-41] Keep related elements together when text wrapping[30] (e.g. active ingredient name and strength)	Standard 1 Supporting strategy 4 Supporting strategy 5 Supporting strategy 6 Supporting strategy 7

Appendix 2 Recommendations from the national roundtable report

The *National Medication Safety and Quality Scoping Study*[3] recommended that standards be developed for dispensed medicine labels, and that the Commission work with pharmacy organisations to develop these standards. The recommendation was supported by findings from the *Consumer Health Forum Workshop*[57], in which consumers expressed concerns about the quality of the content on dispensed medicine labels.

To address these concerns, the Commission and the NSW Clinical Excellence Commission co-hosted a national roundtable on improving the safety and quality of pharmacy-dispensed medicine labels.[1] Participants included representatives from consumer and pharmacy professional organisations, regulatory agencies, universities, medical software industries, pharmacy indemnity insurers and the pharmaceutical industry, and experts in quality use of medicines.

Roundtable participants identified several factors affecting the design and content of dispensed medicine labels, including:

- Legislative requirements
- Software capability and configuration
- Professional standards
- Individual pharmacist preference and communication styles
- Pharmacist understanding and awareness of issues related to health literacy.

The meeting focus was on improving labelling to give consumers the best possible chance of using their medicines safely and effectively.

The roundtable report made 14 recommendations for action (Table A2.1). This standard aims to address these recommendations and provide a national standard to describe the content, format, design and application of dispensed medicine labels.

Table A2.1: Summary of recommendations from the Australian roundtable

No.	Recommendation	Rationale
1.1	A standard should be developed that describes the content, format, design and application of pharmacy dispensing labels	Research in the United States has demonstrated variability in pharmacy dispensing label content. Anecdotally, the variability exists in Australia. For example, label samples obtained from different software providers show considerable variation. Research has explored the effects of different label formats in both prescription and over-the-counter medicines. Principles from the field of graphic design have been applied to improve the readability of labels and guidance developed by the former National Consumer Safety Agency in the *Design for Patient Safety: Guide to the design of dispensed medicines*.[51] Using this information to develop a set of recommendations and templates will result in improved pharmacy dispensing labels
1.2	A standard template should be developed to present information to consumers in a consistent format on pharmacy dispensing medicines labels	
2.1	Consumer-centred content should be of primary importance	The main purpose of the label is to provide the consumer with information about how to take their medicine. In the majority of cases, it is the only source of written information for the consumer on how to take their medicine, including information about dose and frequency
2.2	Medicine name and specific dosage/usage instructions should be placed in greatest prominence	
3.1	Information should be organised in a way that best reflects how most consumers seek out and understand medication instructions	People seek information in specific ways and it is best to present the most important information first. Information is also best understood if grouped according to themes
3.2	Pharmacy dispensing labels should feature only the most important consumer information needed for safe and effective understanding and use	
4.1	Information crucial to safe and effective medicines use should be prominently displayed	Following consumer workshops on labelling and packaging, the Consumers Health Forum of Australia recommended that 'critical information, such as "directions for use", should appear in as large a font as possible to maximise legibility, on at least one face of the presentation. It should not be broken up or separated by non-critical information'
4.2	A standard pharmacy dispensing label format should be developed to guide the display of crucial information. Each element (e.g. medicine name, consumer name) should appear in the same place every time	

continues

Table A2.1: *continued*

No.	Recommendation	Rationale
5.1	Required pharmacy dispensing label information that is not directly related to use instructions (e.g. pharmacy name, phone number, prescriber name, prescription number) should be placed away from dosing instructions to avoid confusion	Medicines labels are required by law to contain information that is unrelated to safe, day-to-day use of the medicine by the consumer. Such information includes a unique dispensing number and the name, address and phone number of the pharmacy. While this information is important, its inclusion reduces the available space for information such as the medicine name, or dose instructions. Approximately a third of the available space is allocated to this information on most standard Australian pharmacy dispensing labels
5.2	Required information that is not directly related to providing instructions on use should be positioned towards the bottom of the pharmacy dispensing label	
6.1	Dosing instructions should be explicit and standardised	Studies conducted in the USA and in Ireland have shown that using explicit instructions for dosing results in improved consumer comprehension. Additionally, there is considerable variation in the way different pharmacists interpret the same prescription. By creating a set of standard, explicit instructions, consumers can be provided with consistent, understandable instructions about dose and interval. Issues associated with lack of explicit instructions have also been cited by consumers during consultation undertaken by the Consumers Health Forum
6.2	Dose should be clearly separated from the interval, and the frequency of the medicine explicit. For example, instructions such as 'take 2 tablets in the morning and 2 tablets at night' should be universally used by pharmacists	
7	A standard minimum font size should be established for each element required on a pharmacy dispensing label	Research has shown that font size is related to the readability of a medicines label as well as the acquisition of information. Increased font size leads to improved acquisition of information on a simulated over-the-counter medicines label. A study conducted in the Dandenong Division of General Practice examined the acceptability and readability of medicines labels produced in large font compared to standard font labels. The study supported the use of increased font size. Consumers have also recommended larger font sizes when consulted
8	A standard, sans serif font should be used for all pharmacy dispensing labels	Font choice affects the readability of medicine labels. A standard font should be used for all labels and should not be compressed or elaborate. Standardising the font also makes it possible to standardise minimum font sizes, as size will vary with font type

continues

Table A2.1: *continued*

No.	Recommendation	Rationale
9	Sentence case should be used including capitalising the first letter of the first word in the sentence	The use of all capitals makes reading more difficult. The shape of words assists in reading them. Lower case letters are constructed from a greater number of unique shapes, creating greater variation in their appearance and less confusion when they are read. For example, the word TRY in upper case has little of the shape it has in lower case (try). Text written in all capitals is read more slowly, and less accurately, than text in lower case
10	Bolding and highlighting should only be used for pharmacy dispensing label information that provides instructions to the consumer (e.g. medicine name and dose)	Typographic techniques are often used to create emphasis on particular words or phrases. These techniques are effective and include such things as bolding and highlighting. These techniques should be used sparingly, and only to draw attention to the information that consumers need in order to use their medicines appropriately
11	A graphic dose matrix, such as that on dose administration aids, should be included in the pharmacy dispensing label	There is benefit in adding a visual dosing guide to the dispensing label for consumers with complex medicine regimens including medicines that are dosed multiple times per day, and for those with low health literacy
12	The indication for use should be included on the pharmacy dispensing label whenever possible and appropriate	Consumers express a desire to have indication included on the pharmacy dispensing label whenever possible. The indication for use is amongst items felt to be most important to consumers
13	Numbers should be presented numerically (2) rather than alphabetically (two)	Numbers are more easily understood if presented numerically rather than alphabetically
14	Auxiliary warning statements should be included on the pharmacy dispensing label in a standardised way	Auxiliary warning labels are frequently overlooked by consumers. This is likely related to both the placement and design of these labels. In addition, the small size font and complicated language used often means that they are not easily read and are poorly understood by consumers

Appendix 3 Qualitative user testing of dispensed medicine labels with consumers

Development of this standard was based on two rounds of user testing with consumers, conducted by the University of Sydney School of Pharmacy.[48] They used an internationally accepted method to evaluate the usability of medicine-related information.[58-60]

Prototype labels for fictitious medicines were developed based on information in the literature, expertise in medicines information design and content, and consumer opinions and information needs. Consumer participants were shown labels with varying formats. Their ability to find and understand key medicine-related information was evaluated. The one-on-one consumer user testing of the labels was followed by a semi-structured interview to investigate consumers' perspectives and identify potential improvements.

Round 1 included a total of 40 participants and tested 12 labels (with each cohort of 10 participants evaluating three unique labels). Round 2 included a total of 20 participants and tested seven labels (with each cohort of 10 participants evaluating three unique labels and one common label).

Label prototypes included variations on dose instructions for:

- An oral solid medicine (tablet and capsule)
- An oral (solid and liquid) medicine that is used only when needed (PRN) and not necessarily daily
- An oral liquid medicine that requires a device to measure the correct volume for administration
- A medicine that is applied to the skin (cream)
- Eye drops.

Overall, most of the evaluated labels met industry standard criteria for user testing in relation to the patient and medicine-related information (excluding the active ingredient and questions on dosing schedule). That is, at least 9 out of 10 participants were able to find the information. Of these, nine participants were able to completely understand the information.

The recommendations from the user testing have been incorporated into this standard and are listed below. Prototype labels are also shown in this appendix. The full report from user testing is available on the Commission's website. Results are published in the journal *Health Expectations*.[61]

Table A3.1: Active ingredient and brand name formatting

Recommendation	Rationale
Signpost the 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 • The brand name sounds like an active ingredient • The active ingredient is not noticeably technical or medical jargon	Explicit signposts ('Active ingredient:' and 'Brand name:') improved participants' ability to explicitly find and understand the active ingredient (and implicitly discern between the brand name and the active ingredient)
If not explicitly specifying the active ingredient, and the brand name (i.e. signposting), consider stating the brand name first followed by the active ingredient in brackets	This reflects current practice, which participants appeared to implicitly understand. Including the active ingredient in brackets improved participants' ability to find it on one set of labels
If not signposting, do not bold the active ingredient and do not place the brand name in brackets	This combination was the least understood option in user testing, as participants spontaneously associated the formatting cues of bold, first in order and not in brackets with the brand name rather than the active ingredient
If not signposting, do not italicise the brand name (especially if presented after or below the active ingredient)	Italics signalled to participants that this was the active ingredient and led to incorrect differentiation between the brand name and the active ingredient

Table A3.2: Communication of medicine-related information

Recommendation	Rationale
Use numbers to convey numerical dosage quantities where appropriate. Consider using words where appropriate	Although no differences were seen in the user testing between the use of numbers or words, participants generally liked the use of numbers, and this also aligns with existing guidelines
Clearly state the specific dosing interval using a narrow range that incorporates some flexibility where appropriate (e.g. 4 to 6 hours, rather than 6 hours). Only include a specific dosing interval (e.g. 6 hours) if this level of specificity is critical to the dosing regimen	A narrow time interval for dosing provides specificity but also some flexibility to allow the person to plan their daily dosing schedule

continues

Table A3.2: *continued*

Recommendation	Rationale
Specify the units immediately after pack size and quantity of medicine (e.g. '100 capsules' not just '100')	This improves clarity
Express medicine strengths using clearer statements. Do not express the medicine strength of an oral liquid dosage form as a concentration alone (e.g. 500 mg/5 mL), where possible	Participants found that the format '500 mg/5 mL' was not clear. Clearer statements can improve understanding, particularly for the oral liquid dosage form. For example, participants liked '500 mg/5 mL' expressed as 'Each 5 mL of syrup contains 500 mg of [active ingredient]'
For non-solid dosage forms, position medicine strength and quantity away from each other	This avoids confusion. For example, when strength and quantity were placed near each other on a label for eye drops, this contributed to worse understanding of medicine strength as the quantity was located and understood to be the medicine strength of 1%
Express discard-by information as weeks where possible, rather than days	Participants reported in qualitative interviews that weeks were easier to understand (for example, 3 weeks rather than 21 days). This may reduce cognitive load by avoiding the need for participants to convert days to weeks. User testing for this standard suggested that there was no difference in participants' ability to determine when the medicine should be discarded, whether the discard-by date was in days or weeks.[48] However, participants reported in qualitative interviews that weeks were easier to comprehend than days[48]
Do not use technical jargon (e.g. 'suspension')	This avoids confusion
Do not place the expiry date and the dispensing date near each other	This avoids confusion

Table 3.3: Design, formatting, and layout

Recommendation	Rationale
Use bullet points for information such as explanations	The explanation of 'empty stomach' using bullet points was preferred by participants in both rounds of user testing
Bold key terms and phrases on label	Bolding for emphasis is part of good writing and design principles, and participants also liked the use of bold. However, it should be used sparingly to preserve impact. Examples of terms or phrases that could be bolded include the dose, dosing interval, maximum daily dose (where applicable), and other key information relevant to dosing such as 'empty stomach'

continues

Table A3.3: *continued*

Recommendation	Rationale
Use a tabular format, where appropriate, to express dosage and frequency of medicine use	Participants found that a table clarifies the dosing regimen
Separate consumer and medicine-specific information from other details included on the label (e.g. pharmacy address, date of dispensing)	This improves clarity
Use either single- or two-column formatting	User testing demonstrated no difference between single- and two-column label formats in whether participants could find and understand information

User testing label prototypes from round 1 and 2

The following prototype labels were user tested in two rounds as part of the development of this standard. The full report from user testing is available on the Commission's website.

Round 1 labels

Label 1
(102 mm × 52 mm)

Myclofenac 75mg Capsules
Vipparoll

Take 1 capsule four times a day

Mr James Douglas
100 Caps Expiry Date: 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 2
(102 mm × 52 mm)

Ocylohydrosteroid
0.5% Cream
Tapisoy

Apply **1 fingertip amount** of cream on the affected skin
Do this:
- in the morning
- at midday
- in the evening
- 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 3
(80 mm × 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 × 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 × 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 × 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 × 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 × 40 mm)

MYCLOFENAC 75mg Tablets
vipparoll

Take 2 tablets every 6 hours, when needed for knee pain

Do not take more than 8 tablets in 24 hours

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 9
(80 mm × 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 × 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 × 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 × 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

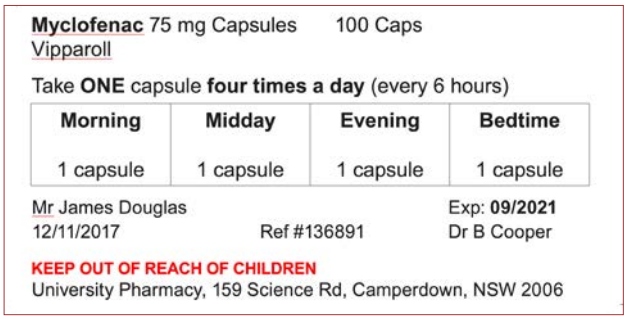
12/11/2017 Dr B Cooper
Ref #136891

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

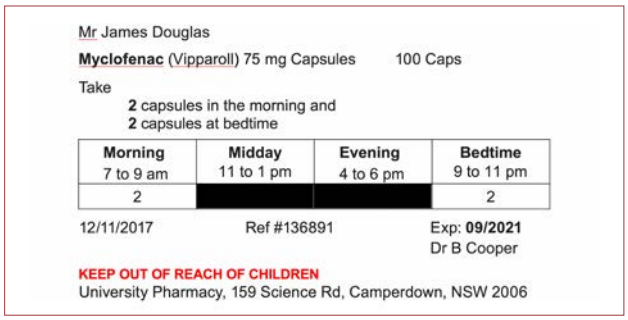
Round 2 labels

Label 13
(80 mm × 40 mm)

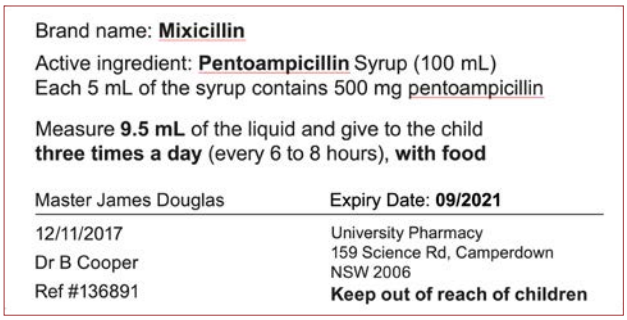
Label 14A
(102 mm × 52 mm)



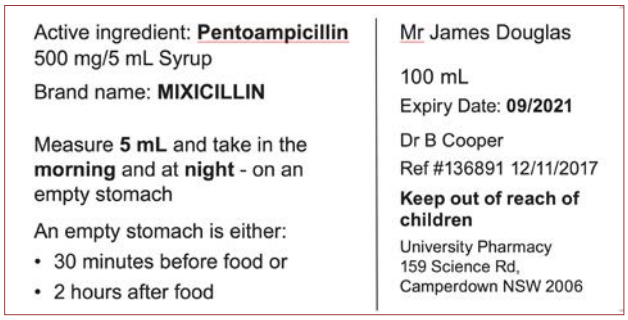
Label 14B
(102 mm × 58 mm)



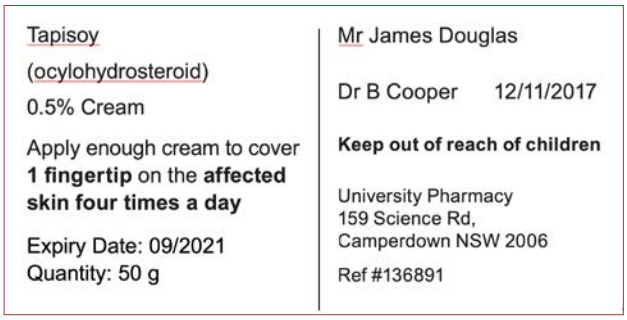
Label 15
(102 mm × 52 mm)



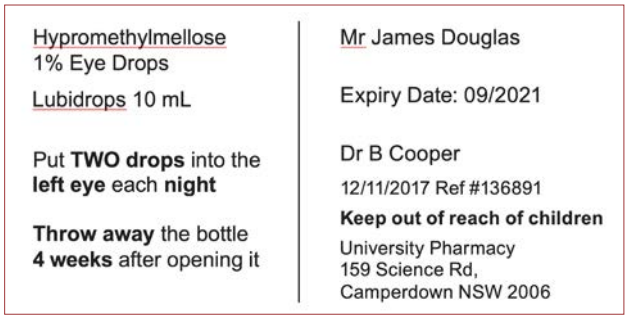
Label 16
(102 mm × 52 mm)



Label 17
(80 mm × 40 mm)



Label 18
(80 mm × 40 mm)



Appendix 4 Quantitative evaluation of dispensed medicine labels

After user testing, revised label prototypes were further evaluated at four Australian hospitals.[62] The recommendations from the quantitative evaluation have been incorporated into this standard. The full report of the evaluation of dispensed medicine labels is available on the Commission's website.

The quantitative evaluation studied the performance of dispensed medicine labels developed from the user testing, patient-centred language and layout, and expert recommendations. The study's objectives were to:

- Explore the impact of labelling characteristics on people's ability to apply dosage-related information
- Compare the performance of the user-tested label prototypes with an implemented label format.

Canberra Hospital, Royal Melbourne Hospital, Royal Darwin Hospital and Palmerston Regional Hospital each conducted a randomised evaluation of dispensed fictitious medicine labels with a diverse group of consumers waiting for hospital discharge. The evaluation tested the impact of label formatting and design on the consumer's ability to locate medicine-related information on a dispensing label.

A total of 16 labels (four label formats, four fictitious medicines) were developed. Labels were randomised into four kits and tested by 275 consumers across the four hospitals. Although the evaluation was conducted in a hospital environment, the findings can be translated across other care settings.

Participants were asked in a questionnaire whether they could identify the following medicine-related information:

- Who the medicine belonged to (consumer name); this question was asked only once per participant for the first label evaluated
- The active ingredient of the medicine
- The medicine strength (amount of active ingredient)
- The dosage prescribed
- How many capsules should be taken over the course of one day (total number of capsules per day).

Participants then showed their understanding of the dosing information by preparing a 24-hour dosette box. The box has 24 wells where each well represents an hour of the day. Participants were asked to place the required number of capsules in the well that represented the time of day they would take the capsules based on the label instructions.

Broadly, the evaluation found that:

- Signposting of the active ingredient – that is, specifying on the label which is the active ingredient and which is the brand name – is the most effective way to help participants identify the active ingredient on the label
- Label formatting that facilitates explicit dosage instructions presented as a list, including specifying times of day, with or without a table, enables most participants to correctly take doses across the day, demonstrated by preparation of a dosette box. An example of explicit instructions would be 'Take 2 tablets in the morning, and 2 tablets in the evening' instead of the more traditional 'Take TWO tablets TWICE a day'
- Improved understanding of medicine instructions and application to dosette packing as a result of improved label formatting and design was more evident in participants with low health literacy.

The testing, results and recommendations reflect consumer understanding of dispensed labelling in both hospital and community settings.

Table A4.1: Recommendations for dispensed medicine labels from the hospital evaluation study

Aspect of label	Recommendation	Rationale/evidence
Active ingredient / brand name formatting	Signpost the active ingredient and brand name on the label	User testing previously found that signposting was the superior approach to communicating active ingredient and brand name information on the label compared with only listing the brand name and active ingredient In this study, label format 3, which included signposting, was the superior label format for communicating active ingredient and brand name
	Include the active ingredient and brand name on separate lines	Label format 1, which had active ingredient presented first and then the brand name second on the line below was the next best labelling option after clear signposting
	Do not include the brand name and active ingredient on the same line together with the active ingredient name in brackets, without other formatting cues	This formatting combination did not perform as well in comparison to clear signposting of the active ingredient and brand name, and the active ingredient first with the brand name second on a separate line It is possible that label formats 2 and 4 did not perform as well because the active ingredient and brand name were positioned together on the same line, brackets were used, and bolding was not used for emphasis and as a cue for the brand name

continues

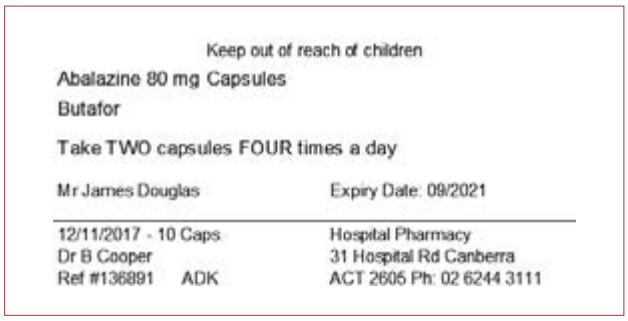
Table A4.1: *continued*

Aspect of label	Recommendation	Rationale/evidence
Communication of medicine-related information	Use explicit labelling directions, where approximate times of day are used to communicate dosage information. For example, 'Take 1 capsule in the morning and 1 capsule in the evening'	Label formats 2 and 4 supported a higher proportion of participants to correctly complete the dosette per medicine, compared with the other two label formats There was no advantage in including the UMS table compared with expressing dosing regimens using standardised UMS approximate times of day. Approximate times of day are preferable, permitting flexibility in dosing and the ability for people to individually tailor their dosing regimens
	Consider people's sleep–wake cycles and daily lifestyles when stating set time frames for medicine taking on the label	This study did not consider factors such as shift work, which can impact medicine taking. For example, people may take medicines at 2 o'clock in the morning. Medicine information included on a label must be tailored to the individual to ensure that it is most appropriate for their given circumstances

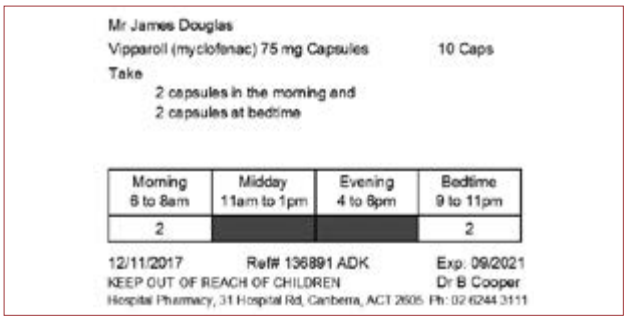
Labels used in quantitative hospital evaluation

A total of 16 labels (four label formats, four fictitious medicines) were developed. Labels were randomised into four kits for evaluation. Each kit contained four labels, representing one of each label format and a fictitious medicine in varying combinations. One example for each of the four label formats are shown below. All labels are provided in the quantitative hospital evaluation report.

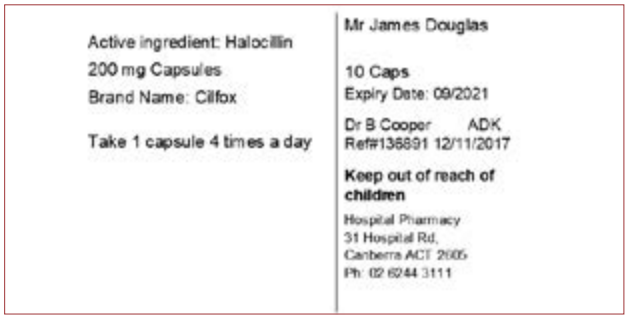
Label format 1



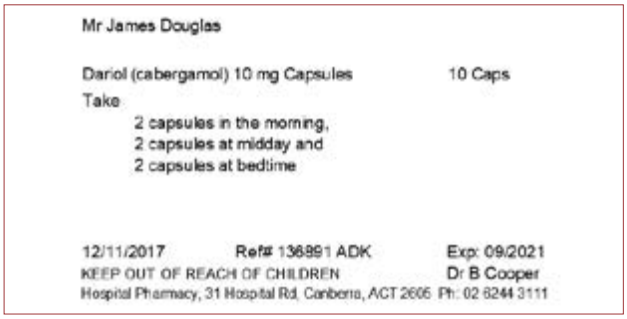
Label format 2



Label format 3



Label format 4



Appendix 5 Pharmacy Board of Australia *Guidelines for Dispensing of Medicines*

Dispensed label requirements are described broadly by the PBA *Guidelines for Dispensing of Medicines*[33]:

> The label of each medicine dispensed must include the particulars required under state and territory legislation, and include:
>
> - in the case of proprietary medicines, the brand and generic names of the medicine, the strength, the dose form and the quantity supplied [in this case 'generic name' refers to active ingredient]
> - in the case of compounded medicines, the name and strength of each active ingredient (especially if a formulation other than a standard pharmacopoeial formulation is used), the name and strength of any added preservatives, the name of the formula as described in a standard pharmacopoeial reference book (where applicable), the dose form and the quantity supplied
> - specific directions for use, including frequency and dose
> - the patient's name or, in the case of an animal, the owner's name and the kind of animal
> - the date of dispensing or supply
> - the initials of the dispensing pharmacist (and if different, the initials of the pharmacist checking and issuing the medicine)
> - a unique identifying code for the dispensed medicine
> - the name, address and telephone number of the pharmacy or pharmacy department at which the medicine was dispensed
> - the applicable storage directions and expiry date of the medicine which are required to facilitate the safe and effective use of the medicine by the patient
> - the words 'Keep out of reach of children', and
> - for compounded medicines, the words 'This product has been compounded by the pharmacist'.

Glossary

Term	Definition
Active ingredient	The therapeutically active component in the medicine's final formulation that is responsible for its physiological or pharmacological action. Display the active ingredient as it appears in the Australian Medicines Terminology.
Brand name	The name given to a medicinal product by the manufacturer. The use of the name is reserved exclusively for its owner. The brand name may also be referred to as a trade name and be used as part of the manufacturer's trademark for that product. Display the brand name as it appears in the Australian Register of Therapeutic Goods.
Complex dose schedule	The schedule for taking a medicine can be complex if it involves multiple doses or units (e.g. number of tablets) to be taken at specific intervals (e.g. every 6 hours) or times during the day (e.g. at 8 am and 4 pm). Other complex dose schedules, such as weekly, alternate days or weaning regimens are out of scope of this standard.
Dispensed medicine label	The label created by the dispensing clinician and attached to the pack of the medicine before providing to the consumer. The dispensed medicine label must include the essential information the consumer needs to take their medicine safely and effectively, as well as other information required by law.
Dispensing clinician	A clinician who dispenses medicines, including pharmacists, pharmacy technicians, nurse practitioners, doctors, dentists and optometrists.
Dosette box	A dose administration aid that organises medicines into separate compartments according to the time of day and day of the week on which they are to be taken.
Dosing information	The amount of a medicine to be taken at any one time. This can be expressed as the number of dosage units (e.g. 1 capsule, 2 tablets), the volume of oral liquid (e.g. 10 mL) or some other quantity (e.g. 2 drops).
Formulation	The physical form of the medicine (e.g. tablets, capsules, oral liquid).
Generic medicine	Once a patent expires, other companies can develop their own versions of the medicine. These are known as generic medicines. Their active ingredient is the same as the originator product but the newer medicines are marketed under different brand names. Some international publications use the term 'generic' to mean 'active ingredient'.
Health literacy	The Commission separates health literacy into two components[2]: • Individual health literacy is the skills, knowledge, motivation and capacity of a person to access, understand, appraise and apply information to make effective decisions about health and health care and take appropriate action • The health literacy environment is the infrastructure, policies, processes, materials, people and relationships that make up the health system and have an impact on the way that people access, understand, appraise and apply health-related information and services.

Term	Definition
Manufacturer's primary pack	The complete pack in which the medicine, or the medicines and their container, are supplied to consumers.[63]
Medicines-use review	Also referred to as a medication review, this can include assessment of current (existing and newly prescribed) medicines, and should be responsive to patients' needs, preferences and medicine-taking behaviour. See also the Medication Safety Standard in the National Safety and Quality Health Service Standards.[64]
Originator product	An 'originator' product or brand (sometimes referred to as the 'innovator' product) is a medicine that has been approved for marketing in Australia on the basis of a full dossier that may include chemical, biological, pharmaceutical, pharmacological–toxicological and clinical data.
Primary medicine container	The medicine container that may be enclosed in a manufacturer's primary pack.
Sans serif font	Serifs are the small lines at the ends of some characters in some fonts. A sans serif font does not have these extra lines, which can make these fonts appear simpler, less cluttered and easier to read.
Secondary packaging	The medicine container that may be enclosed in a manufacturer's primary pack.[63]
Sentence case	The conventional way of using capital letters and lower-case letters in a sentence, where capitals are used only for the first word and proper nouns.
Signposting	Clearly and unambiguously identifying a component of the label by naming that component on the label. For example, active ingredients are signposted by including the text 'Active ingredient:' next to the active ingredient name(s), and brand names are signposted with 'Brand name:' next to the brand name.
Strength	The amount of active ingredient in a medicine formulation.

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