

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using ROSPRID?

ROSPRID contains the active ingredient Prucalopride succinate. ROSPRID tablets are used for the treatment of long-standing constipation in adults in whom conventional medicines used to treat constipation (laxatives) fail to provide adequate relief.

For more information, see Section [1. Why am I using ROSPRID?](#) in the full CMI.

2. What should I know before I use ROSPRID?

Do not use if you have ever had an allergic reaction to ROSPRID or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use ROSPRID?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ROSPRID and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use ROSPRID?

- The usual dose for most patients is one 2 mg tablet once a day. If you are older than 65 years, the starting dose is one 1 mg tablet once a day, which your doctor may increase to 2 mg once a day if needed. Your doctor may also recommend a lower dose of one 1 mg tablet daily if you have severe kidney or liver disease.
- This medicine should be taken with or without food and drinks, at any time once a day.

More instructions can be found in Section [4. How do I use ROSPRID?](#) in the full CMI.

5. What should I know while using ROSPRID?

Things you should do	<ul style="list-style-type: none"> Remind any doctor, dentist or pharmacist you visit that you are using ROSPRID. Tell your doctor immediately if you become pregnant/ if you experience changes in mood or behaviour, or if your depression gets worse while you are taking this medicine.
Things you should not do	<ul style="list-style-type: none"> Do not stop using this medicine suddenly unless your doctor tells you to. Do not use more than your doctor tells you to.
Driving or using machines	<ul style="list-style-type: none"> ROSPRID may cause drowsiness. If affected do not drive or operate machinery or do anything else that could be dangerous.
Looking after your medicine	<ul style="list-style-type: none"> Prucalopride tablets should be kept out of reach of children. Store below 25°C. Store in the original blister in order to protect from moisture.

For more information, see Section [5. What should I know while using ROSPRID?](#) in the full CMI.

6. Are there any side effects?

Prucalopride tablets may cause headache, nausea, weakness, dizziness or spinning sensation (vertigo), fatigue, abnormal bowel sounds, flatulence, general feeling of discomfort or uneasiness (malaise), back pain, decreased appetite, fever, diarrhoea, vomiting, disturbed digestion (dyspepsia), increase in frequency of passing urine (pollakiuria), abdominal pain

Tell your doctor immediately if you notice any of the following:

suicidal thoughts or attempts, tremors, pounding heart, rectal bleeding.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

ROSPRID

Active ingredient(s): *Prucalopride succinate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using ROSPRID. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using ROSPRID.**

Where to find information in this leaflet:

- [1. Why am I using ROSPRID?](#)
- [2. What should I know before I use ROSPRID?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use ROSPRID?](#)
- [5. What should I know while using ROSPRID?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using ROSPRID?

ROSPRID contains the active ingredient **Prucalopride succinate**. ROSPRID acts on the muscle wall of the gut, helping to restore the normal functioning of the bowel.

ROSPRID tablets are used for the treatment of long-standing constipation in adults in whom conventional medicines used to treat constipation (laxatives) fail to provide adequate relief.

ROSPRID is not used to treat constipation due to other medical conditions including disorders which involve the over-production or under- production of hormones from the endocrine gland, disorders that involve an alteration in normal metabolism, disorders of the nervous system and constipation due to use of medicines including opioid medicines such as codeine, oxycodone and morphine.

Your doctor may have prescribed this medicine for another reason. Ask your doctor if you have any questions about why it has been prescribed for you.

There is no evidence that this medicine is addictive.

This medicine is available only with a doctor's prescription.

2. What should I know before I use ROSPRID?

Warnings

Do not use ROSPRID if:

- you are allergic to prucalopride succinate, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- ROSPRID contains lactose. If you have been told by your doctor that you have an intolerance to some

sugars, contact your doctor before taking this medicine.

- Symptoms of an allergic reaction may include rash, itching or hives on the skin, shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body.
- you are on kidney dialysis (a procedure used to remove waste products from the blood of a person with kidney failure)
- if you suffer from perforation or obstruction of the gut wall, or severe inflammation of the intestines
- if you had recent bowel surgery

Check with your doctor if you:

- If you are not sure whether you should take this medicine
- have any other medical conditions, especially the following:
 - severe kidney disease
 - severe liver disease
 - any other serious medical problem such as lung or heart disease, neurological or psychiatric disorders or other endocrine disorders, cancer or AIDS for which you are currently under supervision by your doctor
 - a history of changes in heart rate (fast, slow or irregular) or heart disease caused by reduced blood flow in the blood vessels of the heart muscle
- take any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. It is recommended not to take ROSPRID if you are pregnant or if you intend to become pregnant, unless your doctor advises you to do so.

Talk to your doctor if you are breastfeeding or intend to breastfeed. When breast-feeding, prucalopride can pass into breast milk, and although there is no evidence that this is harmful, it is better not to use this medicine while breastfeeding unless your doctor advises you to do so.

Do not use this medicine:

- If you have not told your doctor about any of the above, tell them before you start taking ROSPRID.
- Do not take this medicine if the packaging is torn or shows signs of tampering.
- Do not take this medicine beyond the expiry date (month and year) printed on the pack.

- The medicine must not be given to children or adolescents (under 18 years of age).

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

In particular, tell your doctor if you are taking the following medicines:

- ketoconazole (an antifungal agent)
- verapamil
- cyclosporine A
- quinidine
- erythromycin (an antibiotic used to treat infections)
- medicines known to cause irregular heart beat or other heart problems
- atropine-like substances
- oral contraceptives

Some medicines may interfere with ROSPRID and affect how it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor or pharmacist will have more information on medicines to be careful with or avoid while taking this medicine.

ROSPRID does not interact with the following medicines: warfarin, digoxin and paroxetine.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ROSPRID.

4. How do I use ROSPRID?

How much to take / use

- The usual dose for most patients is one 2 mg tablet once a day. If you are older than 65 years, the starting dose is one 1 mg tablet once a day, which your doctor may increase to 2 mg once a day if needed. Your doctor may also recommend a lower dose of one 1 mg tablet daily if you have severe kidney or liver disease.
- Follow the instructions provided and use ROSPRID until your doctor tells you to stop.

When to take / use ROSPRID

- ROSPRID should be taken once a day. You must take this medicine every day for as long as your doctor prescribes it.
- Your doctor may want to reassess your condition and the benefit of continued treatment after the first 4 weeks and thereafter at regular intervals.

How to take ROSPRID

- This medicine can be taken with or without food and drinks, at any time of the day.

If you forget to use ROSPRID

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember, and then go back to taking it as you would normally.

Do not take a double dose to make up for the dose you missed.

- This may increase the chance of you getting an unwanted side effect.
- If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you stop taking ROSPRID your constipation symptoms may come back again.

If you use too much ROSPRID

If you think that you have used too much ROSPRID, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling **13 11 26 in Australia**), or (**0800 POISON or 0800 764 766 in New Zealand**)
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

It is important to keep to the dose as prescribed by your doctor. If you have taken more ROSPRID than you should, it is possible that you will get diarrhoea, headache and/or nausea. In case of diarrhoea, make sure that you drink enough water.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

5. What should I know while using ROSPRID?

Things you should do

If you experience severe diarrhoea after taking ROSPRID, certain medicines such as the oral contraceptive pill may not work properly and the use of an extra method of contraception is recommended.

Call your doctor straight away if you:

- become pregnant while you are taking this medicine
- experience changes in mood or behaviour, or if your depression gets worse while you are taking this medicine

Always follow your doctor's instructions carefully.

Remind any doctor, dentist or pharmacist you visit that you are using ROSPRID if you are about to be started on any new medicines.

Things you should not do

- Do not stop using this medicine suddenly or lower the dose without checking with your doctor.
- Do not give your medicine to anyone else, even if they have the same condition as you.
- Do not use this medicine to treat any other complaints unless your doctor tells you to.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how ROSPRID affects you.

ROSPRID has been associated with dizziness and fatigue particularly during the first day of treatment which may have an effect on driving and using machines.

If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Looking after your medicine

- Keep your tablets in their blister pack until it is time to take them.
- If you take the tablet out of the blister pack, they may not keep well.
- Store below 25°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on windowsills.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half meters above the ground is a good place to store medicines.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">• Headache or migraine• nausea	Speak to your doctor if you

<ul style="list-style-type: none">• weakness• dizziness or spinning sensation (vertigo)• fatigue• abnormal bowel sounds• flatulence• general feeling of discomfort or uneasiness (malaise)• back pain	have any of these less serious side effects and they worry you.
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Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">• decreased appetite• fever• diarrhoea• vomiting• disturbed digestion (dyspepsia)• increase in frequency of passing urine (pollakiuria)• abdominal pain	Tell your doctor as soon as possible if you have any of the following as you may need medical attention

Very Serious side effects

Very Serious side effects	What to do
<ul style="list-style-type: none">• suicidal thoughts or attempts• tremors• pounding heart• rectal bleeding	Call your doctor straight away, go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What ROSPRID contains

Active ingredient (main ingredient)	Prucalopride succinate
Other ingredients (inactive ingredients)	Lactose monohydrate Microcrystalline cellulose Magnesium stearate Colloidal anhydrous silica Hypromellose Titanium dioxide Macrogol 400 Polysorbate 80 Iron oxide red (2 mg tablet only)

Do not take this medicine if you are allergic to any of these ingredients.

What ROSPRID looks like

ROSPRID Film-coated tablets are available in two strengths:

1 mg – white to off-white, round, tablets with “C” debossed on one side and “11” on the other side.

2 mg – pink, round, tablets with “C” debossed on one side and “12” on the other side.

Pack sizes:

ROSPRID comes in blister packs of 28 film-coated tablets.

Australian Registration Number

ROSPRID 1 mg tablets- AUST R 358078

ROSPRID 2 mg tablets- AUST R 358079

Who distributes ROSPRID

Medsurge Pharma Pty Ltd
Unit 1&2, 6-7 Gilda Court
Mulgrave, Victoria 3170

Marketed and Distributed by Medsurge Healthcare Pty Ltd.



Telephone: 1300 788 261

Website: www.medsurgehc.com

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