

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 RESOTRANS?

RESOTRANS® contains the active ingredient prucalopride. RESOTRANS® is 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 RESOTRANS®?](#) in the full CMI.

2. What should I know before I use RESOTRANS?

Do not use if you have ever had an allergic reaction to [medicine] 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 RESOTRANS?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with RESOTRANS 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 RESOTRANS?

- 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 RESOTRANS until your doctor tells you to stop.

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

5. What should I know while using RESOTRANS?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Prucalopride.
Things you should not do	<ul style="list-style-type: none">• Do not stop using your medicine suddenly or lower the dose without checking with your doctor.
Driving or using machines	<ul style="list-style-type: none">• Be careful driving or operating machinery until you know how RESOTRANS affects you.
Looking after your medicine	<ul style="list-style-type: none">• Keep your tablets in their blister pack until it is time to take them.• Store the tablets in a cool dry place where the temperature stays below 30°C .

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

6. Are there any side effects?

Prucalopride tablets may cause headache, nausea, weakness, dizziness, fatigue, flatulence, uneasiness, back pain, fever, diarrhea, vomiting, disturbed digestion, abdominal pain, increased urine frequency.

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.

RESOTRANS®

Active ingredient(s): *Prucalopride succinate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using RESOTRANS. **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 RESOTRANS.**

Where to find information in this leaflet:

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

1. Why am I using RESOTRANS?

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

RESOTRANS 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.

RESOTRANS 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 RESOTRANS?

Warnings

Do not use RESOTRANS if:

- you are allergic to prucalopride, the active ingredient in the medicine, or any of the ingredients listed at the end of this leaflet.

- Always check the ingredients to make sure you can use this medicine.
- RESOTRANS 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).
- you suffer from perforation or obstruction of the gut wall, or severe inflammation of the intestines.
- if you had recent bowel surgery.
- If you are not sure whether you should take this medicine, talk to your doctor.

Check with your doctor if you:

- have any other medical conditions
 - 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
- have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

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 RESOTRANS 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.

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.

Some medicines may interfere with RESOTRANS and affect how it works. These include:

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

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.

RESOTRANS does not interact with medicines. These include: 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 RESOTRANS.

4. How do I use RESOTRANS?

How much to take

- 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 RESOTRANS until your doctor tells you to stop.

When to take RESOTRANS

- RESOTRANS should be used should be used 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 RESOTRANS

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

If you forget to use RESOTRANS

RESOTRANS should be used regularly at the same time each day. If you miss your dose at the usual time, and **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 it

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

If you use too much RESOTRANS

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

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- 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.

5. What should I know while using RESOTRANS?

Things you should do

- Always follow your doctor's instructions carefully.
- If you experience severe diarrhoea after taking RESOTRANS, 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
- if you experience changes in mood or behaviour, or if your depression gets worse while you are taking this medicine

Remind any doctor, dentist or pharmacist you visit that you are taking RESOTRANS.

Things you should not do

- 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.
- Do not stop taking your medicine or lower the dose without checking with your doctor.

Driving or using machines

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

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

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

Keep RESOTRANS in a cool dry place where the temperature stays below 30°C.

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 metres above the ground is a good place to store medicines.

Getting rid of any unwanted medicine

If your doctor tells you to stop taking RESOTRANS or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets that are left over.

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.

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• weakness• dizziness or spinning sensation (vertigo)• fatigue• abnormal bowel sounds• flatulence• general feeling of discomfort or uneasiness (malaise)• back pain	Speak to your doctor if you have any of these less serious side effects and they worry you.

<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 these as you may need medical attention.
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Serious side effects

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 or 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 RESOTRANS contains

Active ingredient (main ingredient)	Prucalopride succinate
Other ingredients (inactive ingredients)	<u>For 1 mg tablet</u> lactose monohydrate, microcrystalline cellulose, magnesium stearate, colloidal anhydrous silica Opadry II complete film coating system 33G28707 WHITE

	(ARTG PI No 107234). <u>For 2 mg tablet</u> lactose monohydrate, microcrystalline cellulose, magnesium stearate, colloidal anhydrous silica Opadry II complete film coating system 33G34847 PINK (ARTG PI No 107235).
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Do not take this medicine if you are allergic to any of these ingredients.

What RESOTRANS looks like

RESOTRANS 1 mg tablets are white to off-white, round, biconvex tablets marked PRU 1 on one side.
TGA registration number: AUST R 176747.

RESOTRANS 2 mg tablets are pink, round, biconvex shaped tablets marked PRU 2 on one side.
TGA registration number: AUST R 176746.

Available in pack sizes of 7 and 28 film-coated tablets.

Who distributes RESOTRANS

Amdipharm Mercury (Australia) Pty Ltd

Level 9, 76 Berry Street

North Sydney NSW 2060

Ph: 1800 627 680

Amdipharm Mercury (Australia) Pty Ltd is an ADVANZ PHARMA company

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