

CALOTRANS

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 taking CALOTRANS?

CALOTRANS contains the active ingredient prucalopride succinate, CALOTRANS 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 taking CALOTRANS?](#) in the full CMI.

2. What should I know before I take CALOTRANS?

Do not use if you have ever had an allergic reaction to prucalopride 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 take CALOTRANS?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with CALOTRANS 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 take CALOTRANS?

- Always take this medicine exactly as your doctor or pharmacist has told to you.
- CALOTRANS can be taken with or without food and drinks, at any time of the day.

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

5. What should I know while taking CALOTRANS?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit or any new medicines you are about to start, that you are using CALOTRANS
Things you should not do	<ul style="list-style-type: none">• Do not use any other medicines while taking CALOTRANS unless you have discussed this with your doctor or pharmacist.
Driving or using machines	<ul style="list-style-type: none">• CALOTRANS has been associated with dizziness and fatigue particularly during the first day of treatment which may have an effect on driving and using machines.
Looking after your medicine	<ul style="list-style-type: none">• Keep your medicine in a cool, dry place where the temperature stays below 25°C.• Keep CALOTRANS where children cannot reach it.

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

6. Are there any side effects?

Less serious side effects include headache, nausea, weakness, dizziness, fatigue, flatulence, uneasiness, back pain, fever, diarrhoea, vomiting, disturbed digestion, abdominal pain, increased urine frequency. Serious side effects include 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.

CALOTRANS

Active ingredient(s): *Prucalopride succinate*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I taking CALOTRANS?

CALOTRANS 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.

CALOTRANS 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.

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

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 CALOTRANS?

Do not take CALOTRANS if you have an allergy to:

- prucalopride, the active ingredient in the medicine
- any of the ingredients listed at the end of this leaflet.

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.

Do not take CALOTRANS if:

- 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.
- If you are not sure whether you should take this medicine, talk to your doctor.

Before you start to take CALOTRANS:

Tell your doctor if you have or have had any 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

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

You must tell your doctor if you:

- are pregnant or planning to become pregnant. It is recommended not to take CALOTRANS if you are pregnant or if you intend to become pregnant, unless your doctor advises you to do so.

- are breastfeeding or wish 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.

Warnings

If you have not told your doctor about any of the above, tell them before you start taking CALOTRANS.

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?

Taking other medicines:

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines that you can buy without a prescription from a 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

These medicines may be affected by CALOTRANS or may affect how well 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.

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

4. How do I take CALOTRANS?

Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.

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.

How to take it

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

When to take it

This medicine 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.

If you forget to take it

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 that 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 CALOTRANS, your constipation symptoms may come back again.

If you took too much CALOTRANS

Immediately telephone your doctor or the Poisons Information Centre for advice or go to Accident and Emergency at your nearest hospital, if you think that you have taken too much CALOTRANS. Do this even if there are no signs of discomfort or poisoning. 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.

It is important to keep to the dose as prescribed by your doctor. If you have taken more CALOTRANS 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 taking CALOTRANS?

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

Things you should do

- Always follow your doctor's instructions carefully
- Tell your doctor immediately if you become pregnant while you are taking this medicine
- Tell your doctor immediately if you experience changes in mood or behaviour, or if your depression gets worse while you are taking this medicine
- Tell your doctor or pharmacist that you are taking this medicine if you are about to be started on any new medicines.

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 CALOTRANS affects you.

CALOTRANS 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 medicine in the original pack until it is time to take it. Keep your medicine in a cool, dry place where the temperature stays 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 window sills.

Keep it where young children cannot reach it.

Do not take CALOTRANS after the expiry date.

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

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 • decreased appetite • fever • diarrhoea • vomiting • disturbed digestion (dyspepsia) • increase in frequency of passing urine (pollakiuria) • abdominal pain 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you OR you may need medical attention.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • suicidal thoughts or attempts • tremors • pounding heart • rectal bleeding. 	<p>Stop taking CALOTRANS. 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.</p>

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 CALOTRANS contains

Active ingredient (main ingredient)	Prucalopride succinate
Other ingredients (inactive ingredients)	-Microcrystalline cellulose -Povidone -Magnesium stearate -Opadry II 33G28707 white (ID 107234) [Present in 1 mg only] -Opadry II 33G540029 pink (ID 147774) [Present in 2 mg only]

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

What CALOTRANS looks like

CALOTRANS tablets are available in following strengths:

CALOTRANS 1 mgs: White to off white, round, film-coated tablets, debossed with 'PR1' on one side, plain on the other side and free from physical defects.

CALOTRANS 2mg: Pink, round, film-coated tablets, debossed with 'PR2' on one side plain on the other side and free from physical defects.

The following packs are available:

- OPA/Al/PVC/Al blisters containing 7's, 10's & 28's tablets
- HDPE bottles (with child resistant closure) containing 28's, 30's & 100's tablets

Australian Registration number:

CALOTRANS 1 mg:

- Blister Pack: AUST R 444970
- Bottle Pack: AUST R 444971

CALOTRANS 2 mg:

- Blister Pack: AUST R 444972
- Bottle Pack: AUST R 444973

Who distributes CALOTRANS

Pharmacor Pty Ltd.
CHATSWOOD, NSW 2067,
Australia
www.pharmacor.com.au

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