

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 Rocaltrol?

Rocaltrol contains the active ingredient calcitriol. Rocaltrol is used to treat people with osteoporosis and to prevent osteoporosis in people taking oral corticosteroids. For more information, see Section [1. Why am I using Rocaltrol?](#) in the full CMI.

2. What should I know before I use Rocaltrol?

Do not use if you have ever had an allergic reaction to Rocaltrol 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, are pregnant or plan to become pregnant or are breastfeeding.** For more information, see Section [2. What should I know before I use Rocaltrol?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Rocaltrol 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 Rocaltrol?

- Your doctor will tell you how many Rocaltrol capsules to take each day.
- If you have osteoporosis, the daily dose is usually 0.25 micrograms (one capsule) taken twice daily.

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

5. What should I know while using Rocaltrol?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Rocaltrol.• Do not take any other medicines whether they require a prescription or not without first telling your doctor.• Tell your doctor if you become pregnant while taking Rocaltrol.• Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.• Keep all of your appointments with your doctor so that you progress can be checked.• Discuss your diet with your doctor and adhere strictly to your dietary recommendations.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine suddenly or change the dose without first checking with your doctor.• Do not let yourself run out of Rocaltrol over the weekend or on holidays.• Do not give Rocaltrol to anyone else even if their symptoms seem similar to yours.• Do not use Rocaltrol to treat other complaints unless your doctor says to.
Driving or using machines	<ul style="list-style-type: none">• Your ability to drive a car or operate machinery should not be affected by Rocaltrol.
Looking after your medicine	<ul style="list-style-type: none">• Store below 25°C.• Store in a cool, dry place away from young children.

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

6. Are there any side effects?

Possible side effects include loss of appetite, feeling sick, headache, feeling tired, sleepy or drowsy, fever, vomiting or stomach ache, constipation, weakness or muscle weakness, dry mouth or thirst, irregular and/or rapid heart beat, and urinary tract infection. These are all symptoms of high levels of calcium in the blood. 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.

Rocaltrol®

Active ingredient: calcitriol

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I using Rocaltrol?

Rocaltrol contains the active ingredient calcitriol.

Calcitriol occurs naturally in humans and is a biologically active form of vitamin D.

There are many different types of medicines used to treat bone conditions. Rocaltrol belongs to a group of medicines known as vitamin D compounds.

Rocaltrol is used to treat people with osteoporosis and to prevent osteoporosis in people taking oral corticosteroids.

Rocaltrol capsules are also prescribed by doctors for the treatment of low blood calcium in patients with osteodystrophy (a form of bone disease), hypoparathyroidism (reduced function of the parathyroid glands) and rickets.

Rocaltrol works by improving absorption of calcium from the intestine and by stimulating growth of healthy bones.

2. What should I know before I use Rocaltrol?

Warnings

Do not use Rocaltrol if:

- you are allergic to calcitriol, other vitamin D compounds, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- you have high levels of calcium in your blood (called hypercalcaemia)
- you have vitamin D toxicity.

Check with your doctor if you:

- have any other medical conditions, particularly if you have kidney problems
- take any medicines for any other condition
- you are allergic to any other medicines, foods, dyes or preservatives

If you have not told your doctor about any of the above, tell them before you take any Rocaltrol.

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. Your doctor will discuss the risks and benefits of taking Rocaltrol when pregnant.

Do not take Rocaltrol if you are breastfeeding or intend to breastfeed. Rocaltrol may pass into breast milk and have unwanted effects in the baby.

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 Rocaltrol and affect how it works. These medicines include:

- medicines or vitamin tablets containing vitamin D or calcium
- cholestyramine, medicine used to lower cholesterol levels in the blood
- sevelamer, a medicine used to lower phosphorus levels in your body
- antacids containing magnesium
- digoxin, medicine used to treat heart conditions
- thiazide diuretics, medicines used to treat hypertension (high blood pressure) and oedema (water retention)
- phenytoin and phenobarbital. medicines used to control epilepsy and/or seizures.

These medicines may be affected by Rocaltrol, or may affect how well it works. You may need to take different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

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

4. How do I use Rocaltrol?

How much to take

Your doctor will tell you how many Rocaltrol capsules to take each day. This will vary depending on the nature of your illness, the calcium level in your blood and your individual response to Rocaltrol.

Rocaltrol is usually taken continuously for long term treatment.

Always tell your doctor if you want to stop taking Rocaltrol as stopping suddenly can lead to a rapid fall in calcium levels.

Osteoporosis patients

- Generally the daily dose for adults is 0.25 micrograms (one capsule) taken twice daily.
- Follow the instructions provided and use Rocaltrol until your doctor tells you to stop.

Osteodystrophy, hypoparathyroidism and rickets

- Generally the initial daily dose for adults is 0.25 micrograms (one capsule) given in the morning. If calcium levels have not improved significantly after 2 to 4 weeks treatment with Rocaltrol, your doctor may gradually increase the dose in 0.25 microgram steps until a satisfactory calcium level in your blood is achieved.
- Follow the instructions provided and use Rocaltrol until your doctor tells you to stop.

Paediatric Patients

- The safety and efficacy of Rocaltrol capsules in children has not been sufficiently investigated to enable dosing recommendations.

How to take

- Take Rocaltrol at the same time each day.
- Rocaltrol can be taken with or without food.
- Swallow capsules whole with a glass of water.
- Do not open the capsules and do not take any capsules that are damaged.

If you forget to use Rocaltrol

Rocaltrol should be used regularly at the same time each day. If you miss your dose at the usual time, do not take an extra dose. Wait until the next dose and take your normal dose then.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

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

If you use too much Rocaltrol

If you think that you have used too much Rocaltrol, 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.

The following are some symptoms which may or may not occur:

- loss of appetite
- headache
- excessive thirst
- feeling sick
- vomiting
- constipation

If you are not sure what to do, contact your doctor or pharmacist.

5. What should I know while using Rocaltrol?

Things you should do

- Do not take any other medicines whether they require a prescription or not without first telling your doctor.
- Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed. Otherwise, your

doctor may think that it was not effective and change your treatment unnecessarily.

- Tell your doctor if you feel the capsules are not helping your condition.
- Be sure to keep all of your appointments with your doctor so that your progress can be checked.
- Always discuss with your doctor any problems or difficulties during or after taking Rocaltrol capsules.
- Remind any doctor, dentist or pharmacist you visit that you are using Rocaltrol.
- Tell your doctor if you become pregnant while taking Rocaltrol.

Things you should not do

- Do not suddenly stop taking Rocaltrol or change the dose without first checking with your doctor. Your doctor will tell you the best way to slowly reduce the amount of Rocaltrol you are taking before stopping completely.
- Do not let yourself run out of medicine over the weekend or on holidays.
- Do not give ROCALTROL to anyone else even if their symptoms seem similar to yours.
- Do not use Rocaltrol to treat other complaints unless your doctor says to.

Rocaltrol and diet

You should discuss your diet with your doctor and adhere strictly to your dietary recommendations.

Sudden changes in diet, particularly the amount of dairy products, may lead to increased calcium in your blood. If this happens, you may experience weakness, feeling sick, vomiting, constipation, confusion and increased urination.

Rocaltrol and laboratory tests

Make sure that you keep all blood test appointments with your doctor.

These are to check your blood calcium levels while you are taking Rocaltrol. Your doctor will discuss your specific needs with you.

Driving or using machines

Your ability to drive a car or operate machinery will not normally be affected by Rocaltrol.

Looking after your medicine

- Store below 25°C.
- Keep your capsules in the blister pack until it is time to take them.

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.

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 take Rocaltrol if the package is torn or shows sign of tampering.

Do not use this medicine after the expiry date. If you take this medicine after the expiry date was passed, it may not work as well.

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
Skin related <ul style="list-style-type: none">rash, itching or hives on the skin	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
Gastrointestinal related: <ul style="list-style-type: none">loss of appetitefeeling sickvomiting or stomach acheconstipationdry mouth or thirst Neurological or brain related: <ul style="list-style-type: none">headachefeeling tired, sleepy or drowsy Musculoskeletal or muscle related: <ul style="list-style-type: none">weakness or muscle weakness Cardiovascular or heart related: <ul style="list-style-type: none">irregular and/or rapid heart beat Urinary related: <ul style="list-style-type: none">urinary tract infection Other side effects: <ul style="list-style-type: none">fever	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. These are all symptoms of high levels of calcium in the blood.

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 Rocaltrol contains

Active ingredient (main ingredient)	Calcitriol 0.25 micrograms
Other ingredients (inactive ingredients)	Butylated hydroxyanisole (320) Butylated hydroxytoluene (321) Medium chain triglycerides Gelatin Glycerol Karion 83 Titanium dioxide (171) Iron oxide red (172) Iron oxide yellow (172)
Potential allergens	Rocaltrol does not contain sucrose, gluten, tartrazine or any other azo dyes.

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

What Rocaltrol looks like

Rocaltrol 0.25 microgram capsules are oval with one half brown-orange to red-orange opaque and the other half white to grey-yellow or grey-orange opaque.

Rocaltrol comes in a blister pack of 100 capsules.

(AUST R 92969).

Who distributes Rocaltrol

Clinect Pty Ltd

120-132 Atlantic Drive

Keysborough VIC 3173, Australia

Free Call Australia: 1800 889 005

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