



## Consumer Medicine Information

### ROCALTROL®

Calcitriol

1 microgram per millilitre oral solution

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#### What is in this leaflet

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This leaflet answers some common questions about ROCALTROL oral solution.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of your taking ROCALTROL against the benefits they expect it will have for you.

**If you have any concerns about taking this medicine, ask your doctor or pharmacist.**

**Keep this leaflet with the medicine.** You may need to read it again.

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#### What ROCALTROL is used for

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ROCALTROL contains the active ingredient calcitriol. Calcitriol occurs naturally in humans and is a biologically active form of vitamin D.

ROCALTROL is used to treat people with postmenopausal osteoporosis (bone-thinning) and to prevent osteoporosis in people taking oral corticosteroids. ROCALTROL is also for the treatment of low blood calcium in patients with renal osteodystrophy (a form of bone disease due to failure of the kidneys), hypoparathyroidism from various causes (reduced function of the parathyroid glands, responsible for maintaining the body's calcium level), hyperparathyroidism (excessive levels of the parathyroid hormone in the body) and rickets (vitamin D deficiency).

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

ROCALTROL belongs to a group of medicines known as vitamin D compounds.

Your doctor, however, may have prescribed ROCALTROL for another purpose.

**Ask your doctor if you have any questions why ROCALTROL has been prescribed for you.**

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

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#### Before you take ROCALTROL

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##### ***When you must not take it***

Do not take ROCALTROL if:

- you have had an allergic reaction to ROCALTROL, calcitriol or any other vitamin D-like substances, or any ingredients listed in the Ingredients section of this leaflet



- you have high levels of calcium in your blood (called hypercalcaemia)
  - you have high levels of vitamin D in your blood
  - the package is torn or shows signs of tampering
  - the bottle or dropper are damaged
  - the expiry date printed on the pack has passed
- If you take this medicine after the expiry date has passed, it may not work as well.

**If you are not sure if you should be taking ROCALTROL, talk to your doctor.**

### ***Before you start to take it***

**You must tell your doctor if:**

- **you are pregnant or plan to become pregnant.**  
It is not known whether ROCALTROL is harmful to an unborn baby when taken by a pregnant woman. If there is a need to take ROCALTROL when you are pregnant your doctor will discuss the risks and benefits to you and the unborn baby.
- **you are breastfeeding or plan to breastfeed.**  
Mothers may breastfeed while taking ROCALTROL provided that the calcium levels in the blood of the mother and infant are monitored.
- **you have any other health problems, especially the following:**
  - you are bedridden or in a wheelchair
  - kidney problems
  - vitamin D-resistant rickets (familial hypophosphataemia)
  - irregular and/or rapid heartbeat
  - dehydration
- **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 start taking ROCALTROL.**

### ***Taking other medicines***

**Tell your doctor if you are taking any other medicines including any that you have bought from a pharmacy, supermarket or healthfood shop.**

**Some medicines may interfere with ROCALTROL. These medicines include:**

- medicines or vitamin tablets containing vitamin D, calcium or phosphate
- cholestyramine (Questran Lite<sup>®</sup>)
- if you are undergoing dialysis, antacids or vitamins containing magnesium (e.g. Mylanta<sup>®</sup>, Gaviscon<sup>®</sup>, Mucaïne<sup>®</sup>)
- digoxin (Lanoxin<sup>®</sup>)
- thiazide diuretics (Chlorothiazide (Biomed)<sup>®</sup>, Neo-Naclex<sup>®</sup>)
- antihypertensives with thiazide diuretics (Accuretic<sup>®</sup>, Amizide<sup>®</sup>, Co-Renitec<sup>®</sup>, Hyzaar<sup>®</sup>, Inhibace Plus<sup>®</sup>, Triamizide<sup>®</sup>)
- phenytoin (Dilantin<sup>®</sup>)
- phenobarbital (Phenobarbitone<sup>®</sup>)
- corticosteroids taken by mouth or injection, such as betamethasone, dexamethasone, fludrocortisone, hydrocortisone, methylprednisolone, prednisolone, prednisone or triamcinolone
- phosphate binders, such as aluminium hydroxide (Alu-Tab<sup>®</sup>).

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.



Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking ROCALTROL.

**Ask your doctor or pharmacist if you are not sure about this list of medicines.**

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## **How to take ROCALTROL**

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### ***How much to take***

**Take ROCALTROL exactly as your doctor has prescribed.** Your doctor will tell you how much ROCALTROL to take each day. Sometimes ROCALTROL does not need to be taken every day. This will vary depending on the nature of your condition, the calcium level in your blood and your individual response to ROCALTROL.

Generally, the daily dose for adults ranges from 0.25 to 1 microgram.

### **For infants and small children**

Your doctor will determine the correct dose of ROCALTROL for your child.

Up to the age of 2 years, the normal daily dose ranges from 0.01 to 0.1 microgram per kilogram bodyweight.

### ***How to take it***

ROCALTROL contains a graduated dropper for you to measure the exact dose.

Use the dropper to measure the exact dose of ROCALTROL your doctor has prescribed for you or your child. Place the drops onto a spoon, and mix them into a flavoured drink, such as orange juice.

### ***When to take it***

ROCALTROL can be taken with or without food.

### ***How long to take ROCALTROL***

**Continue taking ROCALTROL until your doctor tells you to stop.**

### ***If you forget to take ROCALTROL***

**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.**

**If you are not sure what to do ask your doctor or pharmacist.**

**If you have trouble remembering your dose, ask your pharmacist for some hints.**

### ***In case of an overdose***

**Immediately telephone your doctor or National Poisons Information Centre (telephone 0800 POISON or 0800 764 766) for advice or go to an Accident and Emergency centre if you think that you or anyone else may have taken too much ROCALTROL, even if there are no signs of discomfort or poisoning.**

You may need urgent medical attention.

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



- loss of appetite
- headache
- vomiting
- constipation

**Keep telephone numbers for these places handy.**

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

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## **While you are taking ROCALTROL**

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### ***Things you must do***

**Tell all doctors, dentists and pharmacists who are treating you that you are taking ROCALTROL.**

**Tell your doctor if you become pregnant while taking ROCALTROL.**

**Do not take any other medicines or dietary supplements, whether they require a prescription or not, without first telling your doctor. You must be especially careful with medicines or dietary supplements that contain vitamin D, calcium or phosphate.**

**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 ROCALTROL is not helping your condition.**

**Be sure to keep all of your appointments with your doctor so that your progress can be checked.**

Your doctor will need to make regular measurements of the calcium level in your blood while you are taking ROCALTROL.

### **ROCALTROL and diet**

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

Sudden changes in diet, particularly the amount of calcium-containing foods, such as dairy products, may lead to increased calcium in your blood. If this happens, you may experience weakness, nausea (feeling sick), vomiting, constipation, confusion, increased urination, headache, loss of interest in everyday activities or loss of appetite.

**You should drink plenty of fluids.**

Not drinking enough fluids can cause a rise in blood calcium levels.

### **ROCALTROL and laboratory tests**

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

These are to check your blood calcium levels (and possibly some other blood factors) while you are taking ROCALTROL. Your doctor will discuss your specific needs with you.

### ***Things you must not do***

**Do not stop taking ROCALTROL or change the dose without first checking with your doctor.** Stopping suddenly can lead in a rapid fall in blood calcium levels.

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.**

### ***Things to be careful of***

**Be careful driving or operating machinery until you know how ROCALTROL affects you.** However, ROCALTROL is not expected to affect your ability to drive a car or operate machinery.

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## **Side Effects**

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**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking ROCALTROL.**

ROCALTROL helps most people but it may have unwanted side effects.

All medicines can have side effects. Sometimes they are serious. You may need medical treatment. **Ask your doctor or pharmacist to answer any questions you may have.**

**Tell your doctor if you notice any of the following and they worry you:**

- rash, itchiness
- nausea (feeling sick)
- vomiting
- metallic taste in the mouth
- stomach ache
- constipation
- diarrhoea
- feeling weak
- headache
- thirst or dry mouth
- tiredness or sluggishness
- loss of appetite
- decreased sexual drive
- muscle pain
- runny nose
- eye infection
- sensitivity to light

These side effects may mean your blood calcium is too high. You should see your doctor as soon as possible.

**Tell you doctor immediately or go to your nearest Accident and Emergency centre if you notice any of the following:**

- severe rash with blisters and bleeding in the lips, eyes, mouth, nose and/or genitals
- bone pain
- dehydration (symptoms include excessive thirst, decreased urine volume, abnormally dark urine, unexplained tiredness, lack of tears when crying, headache, dry mouth, dizziness when standing.)
- vision or hearing disturbances
- confusion and/or trouble thinking and judging clearly
- fever with thirst
- frequent urination and/or pain on urination
- irregular and/or rapid heartbeat

These are all symptoms of high levels of calcium in your blood for a long period of time. These may be serious side effects. You may need urgent medical attention.



This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

**Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.**

**Ask your doctor or pharmacist if you do not understand anything in this list.**

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

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## After taking ROCALTROL

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### ***Storage***

**Keep your medicine in the original container until it is time to take it.**

If you take the medicine out of the original container ROCALTROL solution may not keep well.

The ROCALTROL solution bottle must be tightly closed after use. The original green screw cap can be replaced by the white cap with the dropper. The solution is suitable for use for up to six weeks after the bottle has first been opened.

**Keep ROCALTROL solution in a cool dry place where the temperature stays below 30°C.**

**Do not store it, or any other medicine, in a bathroom or near a sink.**

**Do not leave ROCALTROL in the car or on window sills.**

Heat and dampness can destroy some medicines.

**Keep ROCALTROL 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.

### ***Disposal***

**If your doctor tells you to stop taking ROCALTROL, or it has passed its expiry date, ask your pharmacist what to do with any medicine that is left over.**

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## Product Description

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### ***Availability***

ROCALTROL solution comes in one strength, 1 microgram per millilitre (mL). It comes in a 10 mL bottle in a pack of one.

### ***What ROCALTROL looks like***

ROCALTROL solution 1 microgram per mL is a clear, oily liquid almost colourless to slightly yellowish.

### ***Ingredients***

#### **Active ingredient**

- ROCALTROL solution contains 1 microgram per mL of calcitriol.

#### **Inactive ingredients**



ROCALTROL solution contains butylated hydroxyanisole, butylated hydroxytoluene and medium chain triglycerides.

***Distributor***

ROCALTROL is distributed by:

Roche Products (New Zealand) Limited  
PO Box 12-492  
Penrose  
AUCKLAND

Telephone: (09) 633 0700  
Toll Free: 0800 656 464

This leaflet was prepared on 10 April 2008.

**Reference: New Zealand Data Sheet dated 07 November 2007.**