Rocaltrol®

contains the active ingredient calcitriol

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Rocaltrol capsules.

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 you taking Rocaltrol capsules 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.

What Rocaltrol is used for

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.

Rocaltrol contains calcitriol which 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.

Your doctor, 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.

Rocaltrol is not addictive.

Before you take Rocaltrol

When you must not take it

Do not take Rocaltrol if:

1. **you have had an allergic reaction to Rocaltrol, calcitriol, other Vitamin D compounds, or any ingredients listed at the end of this leaflet**
2. **you have high levels of calcium in your blood (called hypercalcaemia)**
3. **you have vitamin D toxicity**
4. **you are breast-feeding or intend to breast-feed**

   Rocaltrol may pass into breast milk and have unwanted effects in the baby.

Do not take Rocaltrol if the package is torn or shows signs of tampering.

Do not take Rocaltrol if the expiry date (EXP) 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:

1. **you are allergic to any other medicines, foods, dyes or preservatives**
2. **you have any other health problems including:**

- kidney problems.

3. **you are pregnant or intend to become pregnant**

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

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

Some medicines may interfere with Rocaltrol. 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.

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.

How to take 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.

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

Osteoporosis patients

Generally the daily dose for adults is 0.25 micrograms (one capsule) taken twice daily.

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.

Paediatric Patients

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

How to take it

Swallow capsules whole with a glass of water.

Do not open the capsules and do not take any capsules that are damaged.

When to take it

Rocaltrol can be taken with or without food.

How long to take 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.

If you forget to take Rocaltrol

Do not take an extra dose. Wait until the next dose and take your normal dose then.

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

In case of an overdose

If you think that you or anyone else may have taken too much Rocaltrol, immediately telephone your doctor, or Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at your nearest hospital. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Keep telephone numbers for these places handy.

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.

While you are taking Rocaltrol

Things you must do

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

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.

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.

Things you must 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.

Things to be careful of

Your ability to drive a car or operate machinery may be affected by medicines. Normally, your ability to drive a car or operate machinery will not be affected by Rocaltrol.

Side Effects

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 in a few.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

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

- 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
- urinary tract infection

These are all symptoms of high levels of calcium in your blood. If you experience any of these, tell your doctor immediately.

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.

Other side effects not listed above may also occur in some patients:

- rash, itching or hives on the skin

Tell your doctor if you notice anything else that is making you feel unwell.

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.

After taking Rocaltrol

Storage

Keep your capsules in the blister pack until it is time to take them.

If you take the capsules out of the blister pack they may not keep well.

Keep Rocaltrol in a cool dry place where the temperature stays below 25°C.

Do not leave Rocaltrol in direct sunlight.

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

Do not leave it 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 the capsule has passed its expiry date, ask your pharmacist what to do with any capsules that are left over.

Product Description

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.

Ingredients

Active ingredient - calcitriol

- each Rocaltrol capsule contains 0.25 micrograms of calcitriol

Inactive ingredients -

- butylated hydroxyanisole (320)
- butylated hydroxytoluene (321)
- medium chain triglycerides
- gelatin
- glycerol
- karion 83
- and the colours titanium dioxide (171), iron oxide red (172) and iron oxide yellow (172).

Rocaltrol does not contain sucrose, gluten, tartrazine or any other azo dyes.

Distributor

Rocaltrol is distributed by:

Roche Products Pty Limited
ABN 70 000 132 865
Level 8, 30-34 Hickson Road
Sydney NSW 2000.

Medical enquiries: 1 800 233 950

Australian Registration Number

- AUST R 92969

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