

Rocaltrol® 0.25 microgram Capsules

Atnahs

Rocaltrol® 0.5 microgram Capsules

Calcitriol

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Rocaltrol is and what it is used for
2. What you need to know before you take Rocaltrol
3. How to take Rocaltrol
4. Possible side effects
5. How to store Rocaltrol
6. Contents of the pack and other information

1. What Rocaltrol is and what it is used for

Rocaltrol contains a medicine called calcitriol. This belongs to a group of medicines called ‘vitamin D metabolites’.

Rocaltrol is used to treat the following:

- Bone disease in people with kidney problems (renal osteodystrophy).
- Weakening of the bones in women after the menopause (change of life). This is also known as post-menopausal osteoporosis.

Rocaltrol works by making your body absorb more calcium from your diet. This helps to form healthy bones and reduce bone damage.

2. What you need to know before you take Rocaltrol

Do not take Rocaltrol:

if you are allergic (hypersensitive) to:

- Calcitriol or any of the other ingredients of this medicine (listed in section 6).
- Other ‘vitamin D metabolite’ medicines (used to treat bone disease). These include alfacalcidol and colecalciferol.

Do not take Rocaltrol if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Rocaltrol.

Do not take Rocaltrol if:

- You have high levels of calcium in your blood (hypercalcaemia).
- You have extra deposits of calcium in your body (metastatic calcification).
- You are unwell because of high levels of vitamin D in your body.

Do not take Rocaltrol if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Rocaltrol.

Warnings and precautions

Talk to your doctor or pharmacist before taking Rocaltrol if:

- You are finding it difficult to move about (for example, after an operation).
- You have kidney problems (the doctor may need to monitor the phosphate levels in your blood and diet).

Other medicines and Rocaltrol

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription and herbal medicines. This is because Rocaltrol can affect the way some medicines work. Also some other medicines can affect the way Rocaltrol works.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- Other medicines containing vitamin D.
- Diuretics, also called 'water tablets' (used to treat high blood pressure). These include bendroflumethiazide, chlortalidone and indapamide.
- Medicines like digoxin or digitoxin (used to treat heart disease).
- Medicines containing magnesium, such as antacids (used to treat indigestion).
- Steroid medicines, such as hydrocortisone, prednisolone and dexamethasone.
- Cholestyramine, or other 'ion-exchange resins' (used to treat high levels of cholesterol in your blood).
- Phosphate (the doctor may need to monitor phosphate levels in your blood).

Also tell your doctor or pharmacist if you have taken a medicine containing vitamin D over the last few months that has long-lasting effects. These medicines include ergocalciferol and colecalciferol.

Rocaltrol with food and drink

- Do not take any vitamin or food supplements that contain vitamin D while you are taking Rocaltrol.
- Do not eat food which has vitamin D added (food which is 'fortified' with vitamin D) while you are taking Rocaltrol.
- It is very important to keep to any diet that your doctor has given to you.
- If you change how much calcium or vitamin D you have in your diet this can increase the risk of side effects (for example, if you eat more dairy products like milk and cheese, or take vitamins without your doctor knowing).
- Drink plenty of fluids (such as water) as it is important not to become dehydrated. This does not apply if you have kidney problems.

Pregnancy and breast-feeding

- Talk to your doctor before taking Rocaltrol if you are pregnant, think you are pregnant, or plan to get pregnant. Your doctor will then decide if you should take Rocaltrol.
- You can take Rocaltrol if you are breast-feeding. However, your doctor will take blood samples from you and your child to check that there are no unwanted effects.

Driving and using machines

Rocaltrol is not likely to affect you being able to drive or use any tools or machines.

Rocaltrol contains sorbitol

Rocaltrol 0.25 microgram capsules contain 2.87 – 4.37 mg sorbitol per 0.25 microgram capsule

Rocaltrol 0.5 microgram capsules contain 2.87 – 4.36 mg sorbitol per 0.5 microgram capsule

3. How to take Rocaltrol

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

Swallow the capsules whole with a little water.

While you are taking Rocaltrol, your doctor will want you to have regular blood tests to check that the level of calcium in your blood does not get too high.

Bone disease in people with kidney problems (renal osteodystrophy)

- The usual starting dose for adults and elderly people is one 0.25 microgram capsule once a day.
- After 2 to 4 weeks your doctor may start increasing your dose slowly by 0.25 microgram at a time.
- Eventually, depending on your blood test results, your doctor may need to adjust your dose again. He or she may ask you to take Rocaltrol two or three times a week instead of every day. The maximum dose each week is 12 micrograms.

Bone disease after the menopause (post-menopausal osteoporosis)

- The usual dose for adult and elderly women is one 0.25 microgram capsule twice a day.

If you take more Rocaltrol than you should

- If you take more Rocaltrol than you should, talk to a doctor or go to a hospital straight away. Take the medicine pack with you.
- If you take too many capsules, you may get too much calcium in your blood (hypercalcaemia). The signs include loss of appetite, weight loss, feeling sick, being sick, constipation, headache and feeling sluggish, drowsy or weak.

If you forget to take Rocaltrol

- If you forget to take a dose, skip the missed dose. Then take your next dose as normal.
- Do not take a double dose (two doses at the same time) to make up for a forgotten dose.

If you stop taking Rocaltrol

Do not stop taking Rocaltrol without talking to your doctor. This is because weakness of your bones needs long term treatment.

If someone else takes your Rocaltrol capsules by mistake, they should talk to a doctor or go to a hospital straight away.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking Rocaltrol and seek medical help immediately if you have any of the following most serious side effects:

- High levels of calcium in the blood (hypercalcaemia), the signs include loss of appetite, weight loss, feeling sick, being sick, headache and feeling sluggish, drowsy or weak.
- Very high levels of calcium in your blood may lead to high temperature (fever), feeling thirsty, dehydration, passing more water than normal, wetting the bed, constipation, stomach pain, blockage of the bowel and an uneven heartbeat. There may be infections in the bladder and normal growth may stop.
- Allergic reaction (Hypersensitivity), the signs can include itchy skin, skin rashes and reddening of the skin (which may be severe).

Other possible side effects are

Common (may affect up to 1 in 10 people)

- Headache
- Stomach pain or discomfort
- Feeling sick (nausea)
- Rash
- Urinary tract infection

Uncommon (may affect up to 1 in 100 people)

- Decreased appetite
- Vomiting
- Increased levels of creatinine in blood

Not Known (frequency cannot be estimated from the available data)

- Pinkish, itchy swellings on the skin, also called as hives or nettle rash
- Persistent excessive thirst
- Dehydration
- Reduction in weight
- Lack of interest, emotion or feelings (apathy)
- Mental illness with strange or disturbing thoughts or moods
- Weakness of the muscles
- Loss of one or more types of sensory perception
- Sleepiness or drowsiness
- Changes in the rhythm or rate of the heartbeat
- Constipation
- Pain or discomfort in the upper part of the stomach
- Condition where the small bowel does not work properly (paralytic ileus)
- Redness of the skin (erythema)
- Itching
- Retardation in growth
- Passing more urine than normal
- Need to urinate during the night
- Deposition of calcium in the skin (Calcinosis)
- Fever or high temperature
- Thirst

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at:

www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Rocaltrol

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the carton, after EXP. The expiry date refers to the last day of that month.
- Rocaltrol capsules should be kept in their original blisters and outer carton (to protect them from light and moisture).
- Do not store above 25°C.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Rocaltrol contains

Rocaltrol Capsules come in two different strengths.

The active substance in ‘Rocaltrol 0.25 microgram Capsules’ is calcitriol. Each capsule contains 0.25 microgram (a quarter of a microgram) of calcitriol.

The active substance in ‘Rocaltrol 0.5 microgram Capsules’ is calcitriol. Each capsule contains 0.5 microgram (half a microgram) of calcitriol.

Other ingredients in both strength capsules are butylhydroxyanisole (E320), butylhydroxytoluene (E321), medium-chain triglycerides, gelatin, glycerol, sorbitol (E420), mannitol (E421), hydrogenated hydrolysed starch, titanium dioxide (E171), red iron oxide (E172) and yellow iron oxide (E172).

What Rocaltrol looks like and contents of the pack

Rocaltrol 0.25 microgram Capsules are brown-orange to red-orange in colour at one end and white to grey-yellow or grey-orange in colour at the other.

Rocaltrol 0.5 microgram Capsules are brown-orange to red-orange in colour at both ends.

Rocaltrol capsules are supplied in blister packs containing 100 capsules.

Marketing Authorisation Holder and Manufacturer

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