

## PACKAGE LEAFLET: INFORMATION FOR THE USER

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### ROCALTROL

0.25mg capsules, 0.5mg capsules

#### CALCITRIOL

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*• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.*

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*• 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 •*

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#### What is in this leaflet?

1. What ROCALTROL is and what it is used for
2. Before you take ROCALTROL
3. How to take ROCALTROL
4. Possible side effects
5. How to store ROCALTROL
6. Further information

#### 1. WHAT ROCALTROL IS AND WHAT IS IT 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. 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 contains sorbitol, which is a type of sugar. If you have been told by your doctor that you cannot tolerate or digest some sugars (have an intolerance to some sugars), talk to your doctor before taking this medicine.

## **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.

The following side effects may happen rarely with this medicine:

##### **High levels of calcium in your blood**

- 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 heart beat. There may be infections in the bladder and normal growth may stop.
- Occasionally, mental problems may occur. Also there may be deposits of calcium in areas other than your bone (for example, in your kidneys as 'kidney stones'). Your doctor may change your dose of ROCALTROL if this happens.

##### **Kidney**

- Changes in how well your kidney is working (shown by blood tests).

##### **Allergic reactions**

- The signs can include itchy skin, skin rashes and reddening of the skin (which may be severe).

If any of the side effects become serious or troublesome, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

##### **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](http://www.mhra.gov.uk/yellowcard).

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. FURTHER INFORMATION

##### **What ROCALTROL contains**

ROCALTRON Capsules come in two different strengths.

The active substance in 'ROCALTRON 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, butylhydroxytoluene, medium-chain triglycerides, gelatin, glycerol, sorbitol, mannitol, 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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