

## SCHEDULING STATUS

**S4**

## PROPRIETARY NAME, STRENGTH AND DOSAGE FORM

**ROCALTROL® 0,25 µg** (calcitriol 0,25 µg capsule)

**ROCALTROL® 0,50 µg** (calcitriol 0,50 µg capsule)

### Read all of this leaflet carefully before you start using ROCALTROL

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- **ROCALTROL** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

## 1. WHAT DOES ROCALTROL CONTAIN?

The active substance is calcitriol.

The other ingredients are: butylhydroxyanisole, butylhydroxytoluene, medium-chain triglycerides.

Composition of capsule shell: gelatin, glycerol, mannitol, sorbitol, starch, red and yellow iron oxide E172, titanium dioxide E171.

## 2. WHAT ROCALTROL 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.

### 3. BEFORE TAKING ROCALTROL

#### Do not take ROCALTROL if:

- You are allergic (hypersensitive) to calcitriol or any of the other ingredients of ROCALTROL (listed in Section 1 above), or to other 'vitamin D metabolite' medicines (used to treat bone disease). These include alfacalcidol and colecalciferol.
- You have extra deposits of calcium in your body (metastatic calcification).
- You have high levels of calcium in your blood (hypercalcaemia).
- You are unwell because of high levels of vitamin D in your body.

#### Take special care with ROCALTROL:

- If you are finding it difficult to move about (for example, after an operation).

#### Taking 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 Breastfeeding:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before receiving this medicine.

- **Pregnancy:** 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.
- **Breastfeeding:** You should not breastfeed if you are taking ROCALTROL.

**Driving and using machinery:**

ROCALTROL is not likely to affect you being able to drive or use any tools or machines. Determine the effects of ROCALTROL on yourself before driving or using machines.

**Important information about some of the ingredients of ROCALTROL:**

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.

**Using other medicines with ROCALTROL:**

Always tell your healthcare professional if you are taking any other medicine. This includes complementary or traditional medicines.

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 digitalis (used to treat heart disease).
- Medicines containing magnesium, such as antacids (used to treat indigestion).
- Phenytoin or phenobarbitol (used to treat epilepsy).
- Steroid medicines, such as hydrocortisone, prednisolone and dexamethasone.
- Colestyramine, or other 'ion-exchange resins' (used to treat high levels of cholesterol 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.

**4. HOW TO TAKE ROCALTROL**

Do not share medicines prescribed for you with any other person.

Always take ROCALTROL exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Swallow the capsules whole with a little water.

### **Bone disease after the menopause (post-menopausal osteoporosis)**

- The usual dose for adult and elderly women is one 0,25 µg capsule twice a day.

### **Bone disease in people with kidney problems (renal osteodystrophy)**

- The usual starting dose for adults and elderly people is one 0,25 µg capsule once a day.
- After 2 to 4 weeks your doctor may start increasing your dose slowly by 0,25 µg 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.

### **Children**

If ROCALTROL is being given to a child, the doctor will decide the correct dose.

If you have the impression that the effect of ROCALTROL is too strong or too weak, talk to your doctor or pharmacist.

### **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 tablets, you may get too much calcium in your blood (hypercalcaemia). The signs include loss of appetite, feeling sick, being sick, diarrhoea, headache and feeling sluggish, drowsy or weak, feeling thirsty, dehydration, passing more water than normal and an uneven heart beat.

In the event of an overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

### **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.

### **Effects when treatment with ROCALTROL is stopped**

- 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 tablets by mistake, they should talk to a doctor or go to a hospital straight away.

## **5. POSSIBLE SIDE-EFFECTS**

ROCALTROL may have side-effects.

Not all side effects reported for ROCALTROL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ROCALTROL, please consult your doctor, pharmacist or other healthcare professional for advice.

### **The following serious side-effects have been reported:**

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

- The signs include loss of appetite, 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, light sensitivity, passing more water than normal, constipation, stomach pain and an uneven heart beat.
- Also there may be deposits of calcium in areas other than your bone (for example, in your kidneys as 'kidney stones').

#### **Liver**

- Changes in how well your liver 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 you are concerned about these or any other unexpected effect(s), talk to your doctor. If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

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## **6. STORING AND DISPOSING OF ROCALTROL**

Store all medicines out of reach of children.

- ROCALTROL capsules should be kept in their original pack (to protect them from light and moisture) at a temperature below 25°C.
- Do not use ROCALTROL capsules after the expiry date (EXP) stated on the outer pack and label.
- Do not throw away any left over capsules. Instead, return them to your pharmacist so that they can be disposed of carefully. Only keep them if your doctor tells you to.

## **7. PRESENTATION:**

ROCALTROL 0,25 µg: Blister packs or glass bottles containing 30 or 60 capsules.

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## **8. IDENTIFICATION**

ROCALTROL 0,25 µg: Soft gelatin capsules: One half brown-orange to red-orange, opaque and the other half white to grey-yellow or grey-orange, opaque.

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## **9. REGISTRATION NUMBER**

ROCALTROL 0,25 µg: M/22.1.4/84

ROCALTROL 0,50 µg: M/22.1.4/85

## **10. NAME AND ADDRESS OF REGISTRATION HOLDER**

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## **11. DATE OF PUBLICATION**

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