

**Rocaltrol® 0.25 microgram Soft Capsules**

**Roche**

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:**

- 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 used to treat heart disease (like digoxin or digitoxin).
- Medicines containing magnesium, such as antacids (used to treat indigestion).
- Steroid medicines, such as hydrocortisone, prednisolone and dexamethasone.
- Medicines used to treat high levels of cholesterol in your blood (such as cholestyramine, or other 'ion-exchange resins').
- 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**

- If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. 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 have an intolerance to some sugars, contact 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 or pharmacist if you are not sure.

### **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.

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.

#### **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, feeling sick, weight loss, being sick, headache, constipation 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.

#### **See your doctor straight away if you get the following side effects:**

**Allergic reactions** (unknown: frequency cannot be estimated from the available data):

- Sudden swelling of the throat, face, lips or mouth. This can make it difficult to breathe or swallow.
- Sudden swelling of the hands, feet or ankles.
- Skin rash or itching

#### **Other possible side effects:**

Very common: may affect more than 1 in 10 people

High levels of calcium in blood

Common: may affect up to 1 in 10 people

Headache

Stomach pain

Feeling sick

Skin rash

Urinary infections (signs include pain on passing water)

Uncommon: may affect up to 1 in 100 people

Loss of appetite

Being sick

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

Not known: frequency cannot be estimated from the available data

Feeling thirsty

Dehydration

Weight loss

Feeling sluggish

Muscular weakness

Problems with eyesight or hearing

Constipation,

Abdominal pain upper

Redness of the skin

Itching of the skin

Growth problems

Passing more water than normal

Calcium deposits in soft tissues

High temperature

### **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, an uneven heart beat, loss of muscle control, growth problems, problems with eyesight or hearing and urinary infections (signs include pain on passing water).
- 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.

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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

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## **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 to protect the environment.

## 6. Contents of the pack and other information

### What Rocaltrol contains

The active substance is calcitriol. Each capsule contains 0.25 microgram (a quarter of a microgram) of calcitriol.

The other ingredients in the 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 Soft 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 capsules are supplied in blister packs containing 100 capsules.

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**This leaflet was last revised in May 2015**