

PACKAGE LEAFLET: INFORMATION FOR THE USER

CALCITRIOL 0.25 MICROGRAM CAPSULES

Calcitriol Capsules are available in the following strengths: 0.25 and 0.5 microgram. Calcitriol 0.25 microgram Capsules will be referred to as Calcitriol throughout this leaflet.

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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

- What Calcitriol is and what it is used for
- What you need to know before you take Calcitriol
- How to take Calcitriol
- Possible side effects
- How to store Calcitriol
- Contents of the pack and other information

1. What Calcitriol is and what it is used for

Calcitriol is a vitamin D product.

Calcitriol 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.

Calcitriol 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 Calcitriol

Do not take Calcitriol if you are allergic to:

- Calcitriol or any of the other ingredients of this medicine (listed in section 6)
- any other "vitamin D metabolite" medicines (used to treat bone disease). These include alfacalcidol and colecalciferol. Do not take Calcitriol if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Calcitriol.

Do not take Calcitriol if you:

- have high levels of calcium in your blood (hypercalcaemia)
- have extra deposits of calcium in your body (metastatic calcification).
- are unwell because of high levels of vitamin D in your body.
- Do not take Calcitriol if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Calcitriol.

Warnings and precautions

Talk to your doctor or pharmacist before taking Calcitriol if you:

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

Other medicines and Calcitriol

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 Calcitriol can affect the way some medicines work. Also some other medicines can affect the way Calcitriol 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, e.g. 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.

Calcitriol with food and drink

- DO NOT take any vitamin or food supplements that contain vitamin D while you are taking Calcitriol.
- DO NOT eat food which has vitamin D added (food which is 'fortified' with vitamin D) while you are taking Calcitriol.
- 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.

Pregnancy

- Talk to your doctor before taking Calcitriol if you are pregnant, think you may be pregnant or are planning to have a baby, plan to get pregnant. Your doctor will then decide if you should take Calcitriol.

Breast-feeding

- You can take Calcitriol 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

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

Calcitriol contains sorbitol

Calcitriol contains sorbitol, which is a type of sugar. If your doctor has told you that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Calcitriol

Always take Calcitriol exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Swallow the capsules whole with a little water.

While you are taking Calcitriol, 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 recommended 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 Calcitriol 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 recommended dose for adult and elderly women is one 0.25 microgram capsule twice a day.

Use in children

Calcitriol is not recommended for use in children.

If you take more Calcitriol than you should

If you take more Calcitriol 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 Calcitriol

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 Calcitriol

Do not stop taking Calcitriol without talking to your doctor. This is because weakness of your bones needs long term treatment. If someone else takes your Calcitriol 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 Calcitriol 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).

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse. 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.

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

5. How to store Calcitriol

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.

Do not store above 30°C.

Do not transfer them to another container.

Store in the original package.

Do not use Calcitriol after the expiry date that is stated on the outer packaging. The expiry date refers to the last day of that month.

If your capsules appear to be discoloured or show any other signs of deterioration, take them to your pharmacist who will advise you.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Calcitriol contains:

The active ingredient is calcitriol. Each capsule contains 0.25 microgram of calcitriol.

The other ingredients are:

Capsule content: butylated hydroxyanisole (E320), butylated hydroxytoluene (E321) and fractionated coconut oil.

Capsule shell: gelatine, glycerol, sorbitol, titanium dioxide (E171) and quinoline yellow (E104).

Printing ink: refined shellac and black iron oxide (E172).

What Calcitriol looks like and contents of the pack:

Calcitriol are opaque, yellow, oval, soft gelatine capsules imprinted '0.25' in black ink.

Calcitriol is available in bottles containing 30 capsules.

Manufacturer

Manufactured by: RP Scherer GmbH, Postfach 1243, 69412 Eberbach Baden, Germany.

Or

Teva UK Ltd – Brampton Road, Hampden Park, BN229AG Eastbourne, - East Sussex (England)

Or

Pharmachemie B.V. Swensweg, 5 – P.O. Box 552 – RN 2003 Haarlem (Netherlands).

Procured from within the EU and repackaged by: Doncaster Pharmaceuticals Group Ltd., Kirk Sandall, Doncaster, DN3 1QR.

Product Licence holder: Landmark Pharma Ltd., 7 Regents Drive, Prudhoe, Northumberland, NE42 6PX.

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This leaflet only gives a brief outline of some of the more important points about Calcitriol. If you want to know more about these capsules or their effects, please ask your doctor or pharmacist.

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