

<p>Calcitriol 0.25 microgram and 0.5 microgram Capsules calcitriol</p>	<p><i>If you are menopausal and have osteoporosis</i> If you are menopausal and you have been prescribed this medicine to treat osteoporosis, your doctor will carefully check your kidney function and blood calcium levels before starting treatment and at regular intervals during your treatment.</p>
<p>Package leaflet: Information for the user</p>	
<p>Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.</p> <ul style="list-style-type: none"> 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. 	<p>Dehydration If you do not have kidney disease, your doctor will advise you to drink plenty of water during treatment with this medicine to avoid dehydration (losing too much fluid from your body).</p> <p>Children and adolescents Calcitriol should not be given to children and adolescents because the safety and effectiveness of the medicine have not been studied enough in this group of patients to make recommendations about dosage.</p> <p>Other medicines and Calcitriol</p>
<p>What is in this leaflet</p>	
<p>1. What Calcitriol is and what it is used for 2. What you need to know before you take Calcitriol 3. How to take Calcitriol 4. Possible side effects 5. How to store Calcitriol 6. Contents of the pack and other information</p>	<p>Tell your doctor or pharmacist if you are taking/using, have recently taken/used or might take/use 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.</p>
<p>1 What Calcitriol is and what it is used for</p> <p>Calcitriol is a vitamin D product, which is needed for bone formation.</p> <p>Calcitriol is used to treat the following:</p> <ul style="list-style-type: none"> bone disease in people with chronic kidney disease (renal osteodystrophy), especially if you are having haemodialysis (a method of filtering the blood). conditions caused by underactive parathyroid glands (hypoparathyroidism, pseudohypoparathyroidism), which are glands in the neck that release PTH (parathyroid hormone), the hormone that regulates the calcium metabolism. rickets, a condition involving a deficiency in bone formation and development (vitamin D-resistant hypophosphataemic rickets, vitamin D-dependent rickets). a condition associated with overactive parathyroid glands and caused by moderate to severe chronic kidney disease that is not treated with dialysis (secondary hyperparathyroidism in patients with pre-dialysis moderate to severe chronic kidney disease). <p>Calcitriol is also indicated in women with confirmed menopause:</p> <ul style="list-style-type: none"> to treat a condition that weakens the bones and increases the risk of breaking bones (post-menopausal osteoporosis). <p>Calcitriol works by making your body absorb more calcium from your diet. This helps to form healthy bones and reduce bone damage.</p>	<p>In particular, tell your doctor or pharmacist if you are taking any of the following medicines:</p> <ul style="list-style-type: none"> other medicines containing vitamin D, including calcium supplements 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. colestyramine, 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). medicines that make the liver more active, such as phenytoin (used to treat epilepsy) or phenobarbital (a barbiturate). <p>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.</p> <p>Calcitriol with food and drink</p> <ul style="list-style-type: none"> 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. <p>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.</p> <p>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.</p> <p>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.</p> <p>Driving and using machines Calcitriol is not likely to affect you being able to drive or use any tools or machines.</p> <p>Calcitriol contains sorbitol <i>Calcitriol 0.25 microgram Capsules</i> This medicine contains 10.73 mg sorbitol in each capsule. <i>Calcitriol 0.5 microgram Capsules</i> This medicine contains 10.79 mg sorbitol in each capsule. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.</p> <p>Calcitriol contains sodium (component of Quinoline Yellow) This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'.</p>
<p>2 What you need to know before you take Calcitriol</p> <p>Do not take Calcitriol</p> <ul style="list-style-type: none"> if you are allergic to calcitriol or similar medicines or any of the other ingredients of this medicine (listed in section 6). if you have high levels of calcium in your blood (hypercalcaemia). if you have extra deposits of calcium in your body (metastatic calcification). if you are unwell because of high levels of vitamin D in your body. <p>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.</p> <p>Warnings and precautions Talk to your doctor or pharmacist before taking Calcitriol</p> <ul style="list-style-type: none"> if you are finding it difficult to move about (for example, after an operation), in which case there is a higher risk of hypercalcaemia (high levels of calcium in the blood). if you have reduced kidney function (kidney failure), in which case there is a higher risk of calcium building up in areas of your body that do not need it (ectopic calcification) (the doctor may need to monitor the phosphate levels in your blood and diet). If you have a bone formation deficiency (rickets with vitamin D-resistant hypophosphataemia) and are being treated with medicines that contain phosphate. If you are already being treated with ergocalciferol (see section 2 "Other medicines and Calcitriol"). <p>Monitoring levels of calcium and phosphate in the blood There is a close relationship between treatment with this medicine and increased levels of calcium and phosphate in the blood. For this reason:</p> <ul style="list-style-type: none"> during treatment with Calcitriol, follow the diet that your doctor has told you to follow, to avoid a rise in your blood levels of calcium and phosphate (see section 2 "Calcitriol with food and drink"); before and during treatment, your doctor will ask you to have blood tests to check your levels of calcium and creatinine (a protein that is used to check kidney function). If these are too high, your doctor will tell you to stop the treatment immediately until you have normal calcium values again (see section 4 "Possible side effects"); your doctor will check the phosphate levels in your blood; your doctor will tell you how to recognise any symptoms of high calcium and phosphate levels in the blood. 	<p>3 How to take Calcitriol</p> <p>Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.</p> <p>The dose will be decided by your doctor based on your weight and your health. Your doctor will also order frequent blood tests at the start of treatment to find the best dose for you and during treatment to check that the level of calcium in your blood does not get too high.</p>

Bone disease caused by kidney disease in people on dialysis (renal osteodystrophy)

Treatment will be more effective if you take calcium at the same time. Adults need to take a supplement of 600–1000 mg calcium per day.

- The recommended starting dose for adults is 0.25 micrograms daily.
- If you have normal or only slightly reduced blood calcium values, the recommended starting dose is 0.25 micrograms every 2 days.
- If you do not see any improvement after 2 to 4 weeks your doctor may start increasing your dose slowly by 0.25 micrograms daily every 2–4 weeks.
- During treatment, your doctor will adjust the dose between 0.5 micrograms and 1 microgram daily.
- 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.

Menopausal women

If you have a condition that weakens the bones and increases the risk of breaking bones (established post-menopausal osteoporosis)

- The recommended dose for adults is 0.25 micrograms twice daily.
- If your calcium levels do not change much, your doctor will not change the dose.

In this case, your doctor will **not** prescribe treatment with calcium supplements.

If you have a condition associated with overactive parathyroid glands (**secondary hyperparathyroidism**) in patients with pre-dialysis moderate to severe chronic kidney disease):

- The recommended starting dose is 0.25 micrograms once a day in adults.
- If necessary, the dose can be increased to 0.5 micrograms once a day.

If you have a condition associated with underactive parathyroid glands (**hypoparathyroidism**) or you have **rickets**:

- The recommended starting dose is 0.25 micrograms once a day, taken in the morning.
- If you do not see any improvement, your doctor may increase the dose every 2–4 weeks.

Checking calcium levels

Once your doctor has found the right dose, they will check the calcium levels in your blood once a month. Based on these tests, your doctor may also decide to change or temporarily stop your treatment with this medicine (see section 4 “Possible side effects”). While your treatment is stopped/paused, the calcium and phosphate levels in your blood must be monitored every day.

Elderly people

Elderly people do not need a different dosage.

Use in children and adolescents

Calcitriol is not recommended for use in children.

Swallow the capsules whole with a little water.

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 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.

Very common (may affect more than 1 in 10 people)

Common (may affect up to 1 in 10 people)

Uncommon (may affect up to 1 in 100 people)

Rare (may affect up to 1 in 1,000 people)

Very rare (may affect up to 1 in 10,000 people)

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

If you get:

- high levels of calcium or creatinine in the blood, treatment with Calcitriol will be **stopped immediately** until your blood calcium levels go back to normal;
- abnormal levels of calcium and phosphorus in the blood, treatment will be **stopped**.

The possible side effects that you may get with this medicine are listed below by frequency:

Very common (may affect more than 1 in 10 people)

- high levels of calcium in the blood (hypercalcaemia), which can lead to calcium toxicity

Common (may affect up to 1 in 10 people)

- headache
- nausea
- abdominal pain
- urinary tract infections
- rashes

Uncommon (may affect up to 1 in 100 people)

- reduced appetite
- vomiting
- increased creatinine in the blood

Not known (the frequency cannot be determined from the available data)

- allergic reactions (hypersensitivity)
- hives
- needing to drink often (polydipsia)
- dehydration
- weight loss
- feeling indifferent (apathy)
- mental problems
- muscle weakness
- sensory issues
- sleepiness
- uneven heart beat
- constipation
- stomach pain
- blockage of the bowel
- itching
- reddening of the skin (erythema)
- delayed growth
- needing to urinate often (polyuria)
- wetting the bed (nocturia)
- fever
- thirst
- calcium salt deposits in the skin, in the tissues under the skin and, more rarely, in the tendons and the tissues around joints and muscles (calcinosis)

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 Website: 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 Calcitriol

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 outer packaging after EXP. The expiry date refers to the last day of that month.

Store in the original package. Do not store above 30°C.

Do not throw away any medicines via wastewater. 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 Calcitriol contains

- The active substance is calcitriol.
Calcitriol 0.25 microgram Capsules
Each capsule contains 0.25 micrograms calcitriol.
Calcitriol 0.5 microgram Capsules
Each capsule contains 0.5 micrograms calcitriol.
- The other ingredients are fractionated coconut oil, butylated hydroxyanisole (E320), butylated hydroxytoluene (E321), gelatine, glycerol (E422), sorbitol (E420) and the dyes titanium dioxide (E171) and quinoline yellow (E104) (contains sodium).
The 0.5 microgram capsule also includes the dye patent blue (E131).
Both strengths of capsule are printed with black ink that contains shellac (E904) glaze and black iron oxide (E172).

What Calcitriol looks like and contents of the pack

The Calcitriol 0.25 microgram Capsules are opaque, yellow, oval, soft gelatine capsules imprinted ‘0.25’.

The Calcitriol 0.5 microgram Capsules are opaque, green, oblong, soft gelatine capsules imprinted ‘0.5’.

The product is available in pack sizes of 20, 30 and 100 capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX, United Kingdom

Manufacturer

Balkanpharma Dupnitsa AD, 3 Samokovsko Shosse str., Dupnitsa 2600, Bulgaria

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