

CALCITRIOL-GA

calcitriol 0.25 µg capsules

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Calcitriol-GA capsules.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Calcitriol-GA capsules against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Calcitriol-GA is used for

Calcitriol-GA is used to treat people with osteoporosis and to prevent osteoporosis in people taking oral corticosteroids.

Calcitriol-GA capsules are also prescribed by doctors for the treatment of low blood calcium in patients with osteodystrophy (a form of bone disease), hypoparathyroidism (reduced function of the parathyroid glands) and rickets.

Calcitriol-GA works by improving absorption of calcium from the intestine and by stimulating growth of healthy bones.

Calcitriol-GA contains Calcitriol which occurs naturally in humans and is a biologically active form of vitamin D.

There are many different types of medicines used to treat bone conditions. Calcitriol-GA belongs to a group of medicines known as vitamin D compounds.

Your doctor may have prescribed Calcitriol-GA for another purpose.

Ask your doctor if you have any questions why Calcitriol-GA has been prescribed for you.

This medicine is available only with a doctor's prescription.

Calcitriol-GA is not addictive.

Before you take Calcitriol-GA

When you must not take it

Do not take Calcitriol-GA if:

- **You have had an allergic reaction to Calcitriol-GA, calcitriol, other Vitamin D compounds or any ingredients listed in the Ingredients section of this leaflet**
- **You have high level of calcium in your blood (called hypercalcaemia)**
- **You have vitamin D toxicity**
- **You are breastfeeding or intend to breastfeed.**

Calcitriol-GA may pass into the breastmilk and have unwanted effects in the baby.

Do not take Calcitriol-GA if the package shows signs of tampering or if the capsules do not look quite right.

Do not take Calcitriol-GA if the expiry date (EXP) printed on the bottle has passed.

If you take this medicine after the expiry date has passed, it may not work as well.

If you are not sure if you should be taking Calcitriol-GA, talk to your doctor.

Before you start to take it

You must tell your doctor if:

1. **You are allergic to any other medicines, foods, dyes or preservatives**
2. **You have any other health problems including:**
 - kidney problems.
3. **You are pregnant or intend to become pregnant.**

Your doctor will discuss the risks and benefits of taking Calcitriol-GA when pregnant.

If you have not told your doctor about any of the above, tell them before you take any Calcitriol-GA.

Taking other medicines

Tell your doctor if you are taking any other medicines including any that you have bought from a pharmacy, supermarket or health food shop.

Some medicines may interfere with Calcitriol-GA. These include:

- medicines, vitamin tablets containing vitamin D or calcium
- cholestyramine medicine used to lower cholesterol levels in the blood (e.g. Questran Lite®)
- sevelamer, a medicine used to lower phosphorus levels in your body (e.g. Renagel®)
- antacids containing magnesium (e.g. Mylanta®)
- digoxin, medicine used to treat heart conditions (e.g. Lanoxin®)
- thiazide diuretics, medicines used to treat hypertension (high blood pressure) and oedema (water retention) (e.g. Dithiazide®, Moduretic)
- phenytoin (e.g. Dilantin®) and phenobarbital (e.g. Phenobarbitone®), medicines used to control epilepsy and/or seizures.

These medicines may be affected by Calcitriol-GA, or may affect how well it works. You may need to take different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

Your doctor and pharmacist have a complete list of medicines to be careful with or avoid while taking Calcitriol-GA.

Ask your doctor or pharmacist if you are not sure about this list of medicines.

How to take Calcitriol-GA

How much to take

Your doctor will tell you how many Calcitriol-GA capsules to take each day. This will vary depending on the nature of your illness, the level of calcium in your blood and your individual response to Calcitriol-GA.

Your doctor will need to make regular measurements of the calcium level in your blood while you are taking Calcitriol-GA.

Osteoporosis Patients

Generally the daily dose for adults is 0.25 micrograms (one capsule) taken twice daily.

Osteodystrophy, Hypoparathyroidism & Rickets

Generally the initial daily dose for adults is 0.25 micrograms (one capsule) given in the morning. If calcium levels have not improved significantly after 2 to 4 weeks treatment with Calcitriol, your doctor may gradually increase the dose in 0.25 microgram steps until a satisfactory calcium level in your blood is achieved.

Paediatric Patients

The safety and efficacy of Calcitriol-GA capsules in children has not been sufficiently investigated to enable dosing recommendations.

How to take it

Capsules should be swallowed whole with a glass of water.

Do not open the capsules and do not take any capsules that are damaged.

When to take it

Calcitriol-GA can be taken at any time of day with or without food.

How long to take Calcitriol-GA

Calcitriol-GA is usually taken continuously for long term treatment.

Always tell your doctor if you want to stop taking Calcitriol-GA as stopping suddenly can lead to a rapid fall in calcium levels.

If you forget to take Calcitriol-GA

Do not take an extra dose. Wait until the next dose and take your normal dose then.

Do not take a double a dose to make up for one you have missed.

In case of an overdose

If you think that you or anyone else may have taken too much Calcitriol-GA, immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice or go to Accident and Emergency at your nearest hospital. Do this even if there are no signs of discomfort or poisoning.

Keep telephone numbers for these places handy.

You may need urgent medical attention.

The following are some symptoms which may or may not occur loss of appetite, headache, excessive thirst, feeling sick, vomiting and constipation.

If you are not sure what to do, contact your doctor or pharmacist.

While you are taking Calcitriol-GA

Things you must do

Tell all doctors, dentists and pharmacists who are treating you that you are taking Calcitriol-GA.

Do not take any other medicines whether they require a prescription or not without first telling your doctor.

Tell your doctor if you become pregnant while taking Calcitriol-GA.

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

Tell your doctor if you feel the capsules are not helping your condition.

Be sure to keep all of your appointments with your doctor so that your progress can be checked.

Always discuss with your doctor any problems or difficulties during or after taking Calcitriol-GA capsules.

Calcitriol-GA and Diet

You should discuss your diet with your doctor and adhere strictly to your dietary recommendations.

Sudden changes in diet, particularly the amount of dairy products, may lead to increased calcium in your blood. If this happens, you may feel sick, vomit, be confused, experience weakness, be constipated and experience increased urination.

Calcitriol-GA and Laboratory Tests

Make sure that you keep all blood test appointments with your doctor.

These are to check your blood calcium levels while you are taking Calcitriol-GA. Your doctor will discuss your specific needs with you.

Things you must not do

Do not suddenly stop taking Calcitriol-GA or change the dose without first checking with your doctor. Your doctor will tell you the best way to slowly reduce the amount of Calcitriol-GA you are taking before stopping completely.

Do not let yourself run out of medicine over the weekend or on holidays.

Do not give Calcitriol-GA to anyone else even if their symptoms seem similar to yours.

Do not use Calcitriol-GA to treat other complaints unless your doctor says to.

Things to be careful of

Your ability to drive a car or operate machinery may be affected by medicines. Normally, your ability to drive a car or operate machinery will not be affected by Calcitriol-GA.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Calcitriol-GA.

Calcitriol-GA helps most people but it may have unwanted side effects in a few. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Tell your doctor if you notice any of the following and they worry you:

- loss of appetite
- feeling sick
- headache
- feeling tired, sleepy or drowsy
- fever
- vomiting or stomach ache
- constipation
- weakness or muscle weakness

- dry mouth or thirst
- irregular and/or rapid heart beat
- urinary tract infection

These are all symptoms of high levels of calcium in your blood. If you experience any of these, tell your doctor immediately.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

Other side effects not listed above may also occur in some patients:

- Rash, itching or hives on the skin

Tell your doctor if you notice anything else that is making you feel unwell.

Ask your doctor or pharmacist if you do not understand anything in this list.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After taking Calcitriol-GA

Storage

Keep your capsules in the bottle until it is time to take them.

If you take the capsules out of the bottle they may not keep well.

Keep Calcitriol-GA in a cool dry place where the temperature stays below 25°C.

Do not store it, or any other medicine, in a bathroom or near a sink.

Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep Calcitriol-GA where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking Calcitriol-GA, or the capsules have passed their expiry date, ask your pharmacist what to do with any capsules that are left over.

Product Description

What Calcitriol-GA looks like

Calcitriol-GA 0.25 microgram capsules are Red coloured, oval, soft gelatin capsule containing a clear oily liquid.

Ingredients

Calcitriol-GA does not contain sucrose, gluten, tartrazine or any other azo dyes.

Active ingredient - calcitriol

Each Calcitriol-GA capsule contains 0.25 micrograms of calcitriol.

Inactive ingredients -

The capsules also contain:

- butylated hydroxyanisole (320)
- butylated hydroxytoluene (321)
- fractionated coconut oil
- gelatin
- glycerol
- sorbitol and the colours iron oxide red (C177491) and iron oxide yellow (C177492).

Calcitriol-GA is available in bottles or blister pack of 100 capsules.

Australian Registration Number:
AUST R 149504
AUST R 224866

Supplier:

Calcitriol-GA is supplied in Australia by:
Amneal Pharma Australia Pty Ltd
12 River Street
South Yarra VIC 3141

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