

GenRx Calcitriol Capsules

contains the active ingredient, calcitriol

For a copy of a large print leaflet ph: 1800 195 055

Consumer Medicine Information

What is in this leaflet

Read this leaflet carefully before taking your medicine Ask your doctor or pharmacist if you do not understand anything or are worried about taking your medicine.

This leaflet answers some common questions about calcitriol.

It does not contain all the available information.

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

The information in this leaflet was last updated on the date listed on the last page. Some more recent information on your medicine may be available. Speak to your pharmacist or doctor to obtain the most up-to-date information.

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

Keep this leaflet with the medicine.

You may need to read it again.

What calcitriol is used for

The name of your medicine is GenRx Calcitriol. It contains the active ingredient, calcitriol.

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

It is 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.

It works by improving absorption of calcium from the intestine and by stimulating growth of healthy bones.

There are many different types of medicines used to treat bone conditions.

Calcitriol occurs naturally in humans and is a biologically active form of vitamin D.

Your doctor may have prescribed it for another purpose.

Ask your doctor if you have any questions why this medicine has been prescribed for you.

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

There is no evidence that this medicine is addictive.

Before you take calcitriol

When you must not take it

Do not take this medicine if you have had an allergic reaction to calcitriol, to any other medicine containing vitamin D compounds, or any ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include: shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; muscle pain or tenderness or joint pain; or rash, itching or hives on the skin.

Do not take calcitriol if you have high levels of calcium in your blood (called hypercalcaemia).

Do not take calcitriol if you have vitamin D toxicity.

Do not take calcitriol if you are breast-feeding or intend to breast-feed.

Calcitriol may pass into breast milk and have unwanted effects in the baby.

Do not take this medicine if the package is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

Do not take this medicine if the expiry date (EXP) printed on the pack 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 this medicine, 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; you are bedridden or in a wheelchair; vitamin D resistant rickets; an abnormal heartbeat.**
- 3. you are pregnant or intend to become pregnant.**

Your doctor will discuss the risks and benefits of taking calcitriol when pregnant.

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

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and calcitriol may interfere with each other. These include:

- * medicines or vitamin tablets or health supplements containing vitamin D or calcium
- * cholestyramine (Questran Lite(R))
- * antacids containing magnesium (e.g. Mylanta(R))
- * digoxin (Lanoxin(R))
- * thiazide diuretics (e.g. Chlotride(R), Dyazide(R), Moduretic(R))
- * phenytoin (Dilantin(R))
- * Phenobarbital

* Corticosteroids

These medicines may be affected by calcitriol, 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 can tell you if you are taking any of these medicines. They may also have more information on medicines to be careful with or avoid while taking calcitriol.

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

Use in Children

Careful control of dosing and blood levels of calcium is necessary in children on long term therapy to avoid the development of kidney stones.

How to take this medicine

How much to take

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

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

How to take it

Swallow capsules whole with a glass of water.

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

When to take it

Take it at about the same time each day.

Taking your medicine at the same time each day will have the best effect. It will also help you remember when to take it.

Calcitriol can be taken anytime of the day with or without food.

How long to take it

Calcitriol is usually taken continuously for long term treatment.

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

Continue taking your medicine for as long as your doctor tells you.

Make sure you have enough to last over weekends and holidays.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

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

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor, or Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have

taken too much calcitriol.

Do this even if there are no signs of discomfort or poisoning.

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
- * constipation.

While you are taking calcitriol

Things you must do

Tell all doctors, dentists and pharmacists who are treating you that you are taking calcitriol.

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

Tell your doctor immediately if you become pregnant.

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.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

Go to your doctor regularly for a check-up.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects.

CALCITRIOL & 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 experience weakness, feeling sick, vomiting, constipation, confusion and increased urination.

CALCITRIOL & 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. Your doctor will discuss your specific needs with you.

Things you must not do

Do not suddenly stop taking calcitriol 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 you are taking before stopping completely.

Do not give this medicine to anyone else even if their symptoms seem similar to yours.

Do not use this medicine to treat other complaints unless your doctor says to

Do not stop taking your medicine, or change the dosage, without checking with your doctor.

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.

Side Effects of calcitriol

All medicines may have some unwanted side effects. Sometimes they are serious, but most of the time, they are not. Your doctor has weighed the risks of using this medicine against the benefits they expect it will have for you.

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

Ask your doctor or pharmacist to answer any questions you may have.

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

- * loss of appetite
- * feeling sick
- * headache
- * 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.

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 this medicine

Storage

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

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

The capsule colour may change

during storage. This does not affect the quality of the capsule.

Keep this medicine in a cool dry place where the temperature stays below 25 degrees 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 it where 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 this medicine or it has passed its expiry date, ask your pharmacist what to do with any capsules that are left over.

Where to go for further information

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition.

Product Description

What GenRx Calcitriol capsules look like

GenRx Calcitriol 0.25 microgram capsules are oval with one half red and the other half white.

GenRx Calcitriol is available in bottles of 100 capsules.

Ingredients

Active Ingredient:

calcitriol

Each GenRx Calcitriol capsule contains 0.25 micrograms of calcitriol.

Inactive Ingredients:

- * butylated hydroxyanisole (320)
- * butylated hydroxytoluene (321)
- * fractionated coconut oil
- * gelatin
- * glycerol
- * sorbitol and the colours titanium dioxide (C177891), iron oxide red (C177491) and iron oxide yellow (C177492).

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

Australian Registration Number

GenRx Calcitriol 0.25 microgram capsules: AUST R 128750.

Sponsor

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