

APO-Calcitriol Capsules

contains the active ingredient calcitriol

Consumer Medicine Information

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

What is in this leaflet

Read this leaflet carefully before 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. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

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

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

What this medicine is used for

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

It 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.

How it works

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 this medicine

When you must not take it

Do not take this medicine if:

- You have or have had any of the following:
 - Hypercalcaemia (high calcium levels in your blood).
 - Vitamin D toxicity.
- The expiry date (EXP) printed on the blister has passed.
- The packaging is torn, shows signs of tampering or it does not look quite right.
- You are hypersensitive to or have had an allergic reaction to calcitriol, to any other

medicine containing vitamin D compounds, or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body, rash, itching or hives on the skin; fainting or hayfever-like symptoms.

If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

Before you start to take it

You must tell your doctor if:

1. You are allergic to:
 - any other medicines
 - any other substances, foods, dyes or preservatives.
2. You have or have had any medical conditions especially the following:
 - kidney problems
 - you are bedridden or in a wheelchair
 - vitamin D resistant rickets.
3. You are currently pregnant or you plan to become pregnant. Do not take this medicine whilst pregnant until you and your doctor have discussed the risks and benefits involved.
4. You are currently breast-feeding or you plan to breast-feed. Do not take this medicine whilst breastfeeding until you and your doctor have discussed the risks and benefits involved.
5. You are planning to have surgery or an anaesthetic.
6. You are currently receiving or are planning to receive dental treatment.
7. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

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 antacids containing magnesium
- digoxin
- thiazide diuretics
- phenytoin
- phenobarbital.

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.

Follow carefully all directions given to you by your doctor. Their instructions may be different to the information in this leaflet.

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 for

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 to take your next dose, skip the missed dose and take your next dose at the usual time. 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 missed doses.

This may increase the chance of you experiencing side effects.

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

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively go to the Accident and Emergency Department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are taking this medicine

Things you must do

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you are breastfeeding or are planning to breast-feed
- you are about to have any blood tests
- you are going to have surgery or an anaesthetic or are going into hospital.

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.

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

Go to your doctor regularly for a check-up.

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

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:

- Give this medicine to anyone else, even if their symptoms seem similar to yours
- Take your medicine to treat any other condition unless your doctor or pharmacist tells you to
- Stop taking your medicine, or change the dosage, without first 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.

Possible side effects

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

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

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.

Allergic reactions

If you think you are having an allergic reaction to calcitriol, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- cough, shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue, throat or other parts of the body
- rash, itching or hives on the skin
- fainting
- hay fever-like symptoms.

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it 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 will stay below 25°C.

Do not store your medicine, or any other medicine, in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep this medicine 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 or pharmacist tells you to stop taking this medicine or they have passed their expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What APO-Calcitriol look like

APO-Calcitriol 0.25 microgram capsules are red coloured, oval soft gelatin capsules containing a clear oily liquid.

APO-Calcitriol is available in blisters of 100 capsules.

Ingredients

Each APO-Calcitriol capsule contains 0.25 micrograms of calcitriol as the active ingredient.

It also contains the following inactive ingredients:

- butylated hydroxyanisole (320)
- butylated hydroxytoluene (321)
- coconut oil - fractionated

- gelatin
- glycerol
- sorbitol and the colours iron oxide red (C177491) and iron oxide yellow (C177492).

This medicine is gluten-free, lactose-free, sucrose-free, tartrazine-free and free of other azo dyes.

Australian Registration Number

APO-Calcitriol 0.25 microgram capsules:
White opaque PVC/Al blisters of 100 capsules.
AUST R 240872.

Sponsor

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