

# 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

This leaflet answers some common questions about this medicine. 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 this medicine 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 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.

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

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

Your doctor may have prescribed it for another purpose.

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 an allergy to:**

- calcitriol or any other medicine containing vitamin D compounds
- 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

**Do not take this medicine if have any of the following:**

- hypercalcaemia (high calcium levels in your blood)
- vitamin D toxicity

**Do not take this medicine if you are pregnant.**

It may affect your developing baby if you take it during pregnancy. Your doctor will discuss the risks and benefits of taking calcitriol when pregnant.

**Do not breastfeed if you are taking this medicine.**

The active ingredient in this medicine passes into breast milk and there is a possibility that your baby may be affected.

**Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.**

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

**If you are not sure whether you should start taking this medicine, talk to your doctor.**

#### **Before you start to take it**

**Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.**

**Tell your doctor if you have or have had any of the following medical conditions:**

- kidney problems
- you are bedridden or in a wheelchair
- vitamin D resistant rickets

**Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.**

Your doctor can discuss with you the risks and benefits involved.

**If you have not told your doctor about any of the above, tell them before you start taking this medicine.**

### ***Taking other medicines***

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

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

- medicines, vitamin tablets or health supplements containing vitamin D or calcium
- cholestyramine, used to lower cholesterol levels in the blood
- antacids containing magnesium
- sevelamer, used to lower phosphorous levels in your body
- 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 and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

---

## **How to take this medicine**

---

### ***How much to take***

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 your medicine at about the same time each day.

Taking it 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.

### ***If you forget to take it***

**If it is almost time to take 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 experiencing unwanted side effects.

**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 the Poisons Information Centre (telephone 13 11 26) for advice or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much of this medicine.**

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

You may need urgent medical attention.

---

## **While you are taking calcitriol**

---

### ***Things you must do***

**If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking this medicine.**

**Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.**

**If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.**

It may affect other medicines used during surgery.

**If you become pregnant or start to breastfeed while taking this medicine, tell your doctor immediately.**

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

It may interfere with the results of some tests.

**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.

### **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 take this medicine to treat any other complaints unless your doctor tells you to.**

**Do not give your medicine to anyone else, even if they have the same condition as you.**

**Do not stop taking your medicine or lower 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**

---

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

All medicines can have side effects. Sometimes they are serious but most of the time they are not.

**Do not be alarmed by the following lists of side effects. You may not experience any of them.**

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

Tell your doctor or pharmacist 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. Other side effects not listed above may also occur in some patients and there may be some side effects not yet known.

**Tell your doctor or pharmacist if you notice anything that is making you feel unwell.**

---

## **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 see or 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 the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.**

---

## **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. AUST R 240872.

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 and iron oxide yellow.

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

### ***Sponsor***

Apotex Pty Ltd

16 Giffnock Avenue

Macquarie Park NSW 2113

Australia

APO and APOTEX are registered trademarks of Apotex Inc.

This leaflet was last updated in July 2019.