

Calcitriol-AFT

Calcitriol 0.25µg and 0.5µg soft gel capsules

What is in this leaflet

This leaflet answers some common questions about Calcitriol-AFT soft gel 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 your taking Calcitriol-AFT 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-AFT is used for

Calcitriol occurs naturally in humans and is a biologically active form of vitamin D. Calcitriol-AFT is used to treat people with postmenopausal osteoporosis (bone-thinning) and to prevent osteoporosis in people taking oral corticosteroids. Calcitriol-AFT is also for the treatment of low blood calcium in patients with renal osteodystrophy (a form of bone disease due to failure of the kidneys), hypoparathyroidism from various causes (reduced function of the parathyroid glands), hyperparathyroidism (excessive levels of the parathyroid hormone in the body) and rickets (Vitamin D deficiency).

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

This medicine is available only with a doctor's prescription. Your doctor may have prescribed Calcitriol-AFT for another purpose.

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

Before you take Calcitriol-AFT

When you must not take it

Do not take Calcitriol-AFT if:

- you have had an allergic reaction to calcitriol or any other Vitamin D-like substances, or any ingredients listed in the Ingredients section of this leaflet
- you have high levels of calcium in your blood (called hypercalcaemia)
- you have high levels of vitamin D in your blood
- the package is torn or shows signs of tampering
- the expiry date printed on the pack has passed

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

Before you start to take Calcitriol-AFT

You must tell your doctor if:

1. you are pregnant or plan to become pregnant.
It is not known whether Calcitriol-AFT is harmful to an unborn baby when taken by a pregnant woman. If there is a need to take Calcitriol-AFT when you are pregnant your doctor will discuss the risks and benefits to you and the unborn baby.
2. you are breastfeeding or plan to breastfeed.
Mothers may breastfeed while taking Calcitriol-AFT provided that the blood calcium levels of the mother and infant are monitored.
3. you have any other health problems, especially the following:
 - you are bedridden or in a wheelchair
 - kidney problems
 - Vitamin D resistant rickets (familial hypophosphataemia)
 - abnormal heartbeat
 - you are allergic to any other medicines, foods, dyes or preservatives
4. you are taking any other medicines including any that you have bought from a pharmacy, supermarket or healthfood shop.

Some medicines may be affected by or interfere with how well Calcitriol-AFT works. You may need to take different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

These medicines include:

- medicines or vitamin tablets containing vitamin D or calcium
- cholestyramine (Questran Light[®])
- if you are undergoing dialysis, antacids containing magnesium (e.g. Mylanta[®], Gastrogel[®], Gaviscon[®], Mucaïne[®])
- digoxin (Lanoxin[®])
- thiazide diuretics (e.g. Chlotride[®], Navidrex[®], Neo-naclex[®])
- antihypertensives with thiazide diuretics (Accuretic[®], Amizide[®], Co-Renitec[®], Inhibace Plus[®], Triamizide[®])
- phenytoin (Dilantin[®])
- phenobarbital (Gardenal[®])
- corticosteroids taken by mouth or injection - prednisone, prednisolone, methylprednisolone, betamethasone, cortisone, dexamethasone, budesonide, hydrocortisone, fludrocortisone.

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

How to use the Medicine

How much to take

Your doctor will tell you how much Calcitriol-AFT to take each day. Sometimes Calcitriol-AFT does not need to be taken every day. This will vary depending on the

nature of your condition, the calcium level in your blood and your individual response to the medicine.

Generally the daily dose for adults ranges from 0.25 to 1.00 micrograms

How to take it

Calcitriol-AFT capsules should be swallowed whole with a glass of water. Do not open or bite the capsules and do not take any capsules that are damaged.

When to take it

Calcitriol-AFT can be taken with or without food.

How long to take Calcitriol-AFT

Continue taking Calcitriol-AFT until your doctor tells you to stop.

If you forget to take Calcitriol-AFT

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 it as you would normally.

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

If you have trouble remembering your dose, ask your pharmacist for some hints.

Things you must do

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

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

Do not take any other medicines or dietary supplements whether they require a prescription or not, without first telling your doctor. You must be especially careful with medicines or dietary supplements that contain Vitamin D, calcium or phosphate.

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 Calcitriol-AFT is not helping your condition.

Be sure to keep all of your appointments with your doctor so that your progress can be checked. Your doctor will need to make regular measurements of the calcium level in your blood while you are taking Calcitriol-AFT.

Calcitriol-AFT 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 calcium containing foods, such as dairy products, may lead to increased calcium in your blood. If this happens, you may experience weakness, feeling sick, vomiting, constipation, confusion, increased urination, headache, loss of interest in everyday activities or loss of appetite.

Calcitriol-AFT and Laboratory Tests:

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

These are to check your blood calcium levels (and possibly some other blood factors) while you are taking Calcitriol-AFT. Your doctor will discuss your specific needs with you.

Things you must not do

Do not stop taking Calcitriol-AFT or change the dose without first checking with your doctor.

Stopping suddenly can lead in a rapid fall in blood calcium levels.

Your doctor will tell you the best way to slowly reduce the amount of Calcitriol-AFT you are taking before stopping completely.

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

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

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

Things to be careful of

Be careful driving or operating machinery until you know how Calcitriol-AFT affects you.

However, Calcitriol-AFT is not expected to affect your ability to drive a car or operate machinery.

Side effects

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

Calcitriol-AFT helps most people but it may have unwanted side effects.

All medicines can have side effects. Sometimes they are serious. 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:

- dehydration
- rash, itchiness

- nausea
- loss of appetite
- headache
- stomach ache, constipation.

Tell your doctor immediately or go to your nearest Accident and Emergency centre if you notice any of the following:

- weakness, tiredness
- vomiting
- sight or hearing disturbances
- confusion
- fever and a dry mouth, thirst
- frequent urination and/or pain on urination
- loss of interest in everyday events
- irregular heartbeat.

These are all symptoms of high levels of calcium in your blood. These may be serious side effects and you may need urgent medical attention.

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.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

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

Overdose

Immediately telephone your doctor or National Poisons Information Centre (telephone 0800 POISON or 0800 764 766) for advice or go to an Accident and Emergency centre if you think that you or anyone else may have taken too much Calcitriol-AFT, 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
- vomiting
- constipation

Keep telephone numbers for these places handy.

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

Storage

Keep your medicine in the original container until it is time to take it.

If you take the medicine out of the original container Calcitriol-AFT capsules may not keep well.

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

Do not store them, or any other medicine, in a bathroom or near a sink. Do not leave them in the car or on window sills. Heat and moisture can destroy some medicines.

Keep Calcitriol-AFT 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-AFT, or it has passed its expiry date, ask your pharmacist what to do with any medicine that is left over.

Other ingredients

The capsule shell is made from gelatin, glycerol, sorbitol, sodium ethyl-p-hydroxybenzoate, sodium propyl-p-hydroxybenzoate and titanium dioxide. The 0.25µg strength capsule contains also contains red iron oxide as a colourant while the 0.5µg strength capsule contains both red and yellow iron oxides as colourants. Each capsule also contains butylated hydroxyanisole (BHA), butylated hydroxytoluene (BHT) and medium-chain triglycerides.

Distributor

New Zealand:
AFT Pharmaceuticals Ltd.,
Auckland

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