

Package leaflet: Information for the user

Alfacalcidol Crinex 0,25 microgram, zachte capsules

Alfacalcidol Crinex 0,5 microgram, zachte capsules

Alfacalcidol Crinex 1 microgram, zachte capsules

alfacalcidol

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Alfacalcidol Crinex is and what it is used for
2. What you need to know before you take Alfacalcidol Crinex
3. How to take Alfacalcidol Crinex
4. Possible side effects
5. How to store Alfacalcidol Crinex
6. Contents of the pack and other information

1. What Alfacalcidol Crinex is and what it is used for

Alfacalcidol Crinex belongs to a group of medicines called vitamin D analogues. It is a type of vitamin D.

Vitamin D controls the levels of two substances in your body. These substances are called calcium and phosphate. Your body needs both of these substances for healthy bones and teeth.

This medicine works by increasing the amount of vitamin D in your body. This means the levels of calcium and phosphate in your body will increase too.

This medicine is indicated in children above 4 years, adolescents and adults.

This medicine is used to treat diseases where the amount of calcium in your body needs changing. It is used to treat the following conditions:

- When the parathyroid glands become overactive in people with kidney problems, including those on dialysis, affecting calcium and bone health (Severe or progressive secondary hyperparathyroidism in patients with kidney problems, including those on dialysis).
- When the parathyroid glands do not make enough hormone, leading to low calcium and weaker bones (Low parathyroid hormone levels [hypoparathyroidism]).
- Rare types of rickets or soft bones caused by a lack of vitamin D (Pseudo-deficiency [D-dependent] rickets and osteomalacia).
- Rare forms of rickets or soft bones caused by low phosphate in the blood that do not respond to vitamin D (Hypophosphataemic vitamin D resistant rickets and osteomalacia).

2. What you need to know before you take Alfacalcidol Crinex:

Do not take Alfacalcidol Crinex:

- if you are allergic to active substance or any of the other ingredients of this medicine (listed in section 6).
- If you know you have a condition called hypercalcaemia. This means you have high levels of calcium in your blood.
- If you are unsure if any of the above apply to you, talk to your doctor before taking this medicine.

Warnings and precautions

Talk to your doctor before taking this medicine:

- if you are taking another type of medicine called a cardiac glycoside, such as digoxin. These medicines are used to treat problems with your heart.

You may get too much calcium or phosphate in your blood when you take this medicine. Please read section 4 of this leaflet so you can spot any signs this may be happening to you. Your doctor may need to change your dose.

While you are taking this medicine your doctor will take regular blood tests. This is very important in children, patients with kidney or liver problems, or patients on a high dose of medicine. This is to check the level of calcium and phosphate in your blood while you take your medicine and adjust your dose if needed.

Your doctor may prescribe another medicine called a phosphate binding agent to take as well as this medicine. This will help to keep the right amount of phosphate in your blood.

Children and adolescents

Other formulations of alfacalcidol are available for children if a dose less than 0.25 micrograms needs to be administered or for children younger than 4 years or for children unable to swallow capsules.

Other medicines and Alfacalcidol Crinex

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

You must tell your doctor or pharmacist if you are taking any of the following medicines:

- Anticonvulsants (e.g. carbamazepine or primidone): for epilepsy or fits. You may need a larger dose of this medicine.
- Barbiturates: for sleeping disorders. You may need a larger dose of alfacalcidol
- Cardiac glycosides, such as digoxin: for heart problems. You may get too much calcium in your blood. This may cause an abnormal heart beat.
- Colestyramine: for lowering your cholesterol level, or to help stop some types of diarrhea or itching. Your alfacalcidol may not enter your blood as usual.
- Thiazide diuretics, often called "water pills": for increasing the amount of water (urine) that your body makes. You may get too much calcium in your blood.
- Magnesium based antacids and laxatives: You may get too much magnesium in your blood.
- Vitamin D or its analogous and calcium or calcium containing preparations: for calcium deficiency. You may get too much calcium in your blood.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Tell your doctor if you become pregnant while taking this medicine.

Driving and using machines

Usually your medicine may have very little effect on your ability to drive or use machines. Check with your doctor if you feel any side effect that may stop you from driving or using machines.

Alfacalcidol Crinex contains sorbitol:

This medicine contains 22 mg sorbitol in each dosage unit.

Sorbitol is a source of fructose. If you (or your child) have hereditary fructose intolerance (HFI), a rare genetic disorder, you (or your child) must not receive this medicine. Patients with HFI cannot break down fructose, which may cause serious side effects.

You must tell your doctor before receiving this medicine if you (or your child) have HFI or if your child can no longer take sweet foods or drinks because they feel sick, vomit or get unpleasant effects such as bloating, stomach cramps or diarrhoea.

3. How to take use Alfacalcidol Crinex

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will tell you how many capsules to take, or to give your child.

At first you will have weekly blood tests to check the levels of some substances in your blood. These tests are to check the levels of calcium, an enzyme called alkaline phosphatase or the parathyroid hormone. This is so your doctor knows that you are taking the dose that is right for you. When you are getting the correct dose you will not need blood tests so often.

You may also have other tests such as X-rays. This is also so your doctor knows that the dose is right for you.

Your doctor may adjust your dose. Your doctor may ask you to take more or less capsules depending on your test results.

You may get too much calcium or phosphate in your blood when you take this medicine. Please read section 4 of this leaflet so you can spot any signs this may be happening to you.

Your doctor will tell you not to take any more medicine. You will need to have some blood tests. When the blood tests are normal your doctor will tell you to start your medicine again. The dose will then be half the dose you had before. It is important that you only take half the dose you had before.

The recommended dose is:

Adults

The usual starting dose is 0.25-0.50 microgram each day.

Most people take between 0.25 and 1 microgram each day once the blood test results show the medicine is working.

If you have very low levels of calcium in your blood, your doctor may prescribe between 3 and 5 microgram each day. Your doctor may additionally prescribe another medicine called calcium supplement to take as well. This will help to keep the right amount of calcium level in your blood.

Use in children above 4 years:

The usual starting dose is 0.25-0.50 microgram each day.

Other formulations are available in case a dosage less than 0.25 micrograms needs to be administered for children younger than 4 years or in case children are unable to swallow capsules.

If you take more Alfacalcidol Crinex than you should

Tell your doctor straight away. You may need to stop taking this medicine.

You may get too much calcium or phosphate in your blood. Please read section 4 of this leaflet so you can spot any signs this may be happening to you.

If you forget to take Alfacalcidol Crinex

Do not take a double dose to make up for a forgotten dose.

If you forget to take your medicine, take it as soon as you remember. Then take the next dose at the usual time.

If you have any further questions about taking this medicine, please ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Important side effects to look out for:

You must get urgent medical help if you have any of the following symptoms. You may be having an allergic reaction:

- you have difficulty breathing
- your face or throat swell
- your skin develops a severe rash.

You should tell your doctor straight away if you spot any of the following signs which may be due to too much calcium or phosphate in your blood. These side effects are common (may affect up to 1 in 10 people):

- you feel weak or have pain in your muscles or bones
- you need to pass water (urine) more often
- you feel thirsty
- you feel fatigue
- you feel sick, vomit, have constipation or have lost your appetite
- you are sweating a lot
- you are having headache
- you feel confused
- you feel drowsy.

You should tell your doctor as soon as possible if you spot any of the following signs which may be due to problems developing with your kidneys. The frequency of these side effects is uncommon (may affect up to 1 in 100 people)

- kidney problems
- needing to pass water (urine) less often
- swelling of any parts of your body
- fever with a pain in your side.

Kidney stones may be forming. Kidney stones may cause a sharp spasm in one side of your lower back.

Other possible side effects

Common possible side effects which may affect up to 1 in 10 people:

- abdominal/stomach pain or discomfort
- rash
- hypercalciuria (increased levels of calcium in the urine)
- itch.

Uncommon possible side effects which may affect up to 1 in 100 people:

- headache

- diarrhoea, vomiting, constipation, nausea
- fatigue
- calcinosis (deposits of calcium in the body)
- feeling weak or unwell.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system Nederlands Bijwerkingen Centrum Lareb. Website: www.lareb.nl.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Alfacalcidol Crinex

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Alfacalcidol Crinex contains

- The active substance is alfacalcidol.
- Each soft capsule contains 0.25 microgram, 0.5 microgram or 1 microgram alfacalcidol.

The other ingredients are:

Capsules fill - butylated hydroxyanisole (E320), butylated hydroxytoluene (E320), triglycerides, medium-chain

Capsule shell - gelatin (E441), glycerol (E422), sorbitol liquid (non-crystallising) (E420)

Capsule shell colours - 0.25 microgram capsules: titanium dioxide (E171); 0.5 microgram capsules: titanium dioxide (E171), allura red AC (E129), brilliant blue FCF (E133) and iron oxide yellow (E172); 1 microgram capsules: iron oxide black (E172) and iron oxide red (E172).

What Alfacalcidol Crinex looks like and contents of the pack

Alfacalcidol Crinex 0.25 microgram: opaque white, oval shaped soft gelatin capsules containing clear colourless, oily liquid. The size is approximately 9.7 mm X 6.8 mm.

Alfacalcidol Crinex 0.5 microgram: opaque red, oval shaped soft gelatin capsules containing clear colourless, oily liquid. The size is approximately 9.7 mm X 6.8 mm.

Alfacalcidol Crinex 1 microgram: opaque brown, oval shaped soft gelatin capsules containing clear colourless, oily liquid. The size is approximately 9.7 mm X 6.8 mm.

Alfacalcidol Crinex is available in PVC/PVDC Film/Aluminium blister packs containing 30, 60, 90 or 120 capsules.

Not all pack sizes may be marketed.

Houder van de vergunning voor het in de handel brengen en fabrikant

Vergunninghouder

LABORATOIRES CRINEX

1 B Rue Rene Anjoly

94250 Gentilly

Frankrijk

Fabrikant

Copea Pharma Europe Limited
Unit 2, Medici House
Ashbourne Manufacturing Park
Ashbourne, A84 KH58
Ierland

In het register ingeschreven onder:

Alfacalcidol Crinex 0,25 microgram, zachte capsules - RVG 134933
Alfacalcidol Crinex 0,5 microgram, zachte capsules - RVG 134936
Alfacalcidol Crinex 1 microgram, zachte capsules - RVG 134937

Dit medicijn is geregistreerd in lidstaten van de Europese Economische Ruimte onder de volgende namen:

Nederland: Alfacalcidol Crinex 0,25 microgram, zachte capsules
 Alfacalcidol Crinex 0,5 microgram, zachte capsules
 Alfacalcidol Crinex 1 microgram, zachte capsules

Frankrijk: Alfacalcidol Crinex

Deze bijsluiter is voor het laatst goedgekeurd in juli 2026.