

ALFOST 0.25MCG, 0.5MCG & 1 MCG

Alfacalcidol Capsules

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What Alfost is used for

Alfost contains Alfacalcidol and 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.

- Low levels of calcium in the blood of newborn babies (hypocalcaemia).
- Softening and deformity of the bones due to lack of calcium (rickets or osteomalacia).
- Disorders of the parathyroid glands (Hypoparathyroidism)
- Decrease in bone mass and density (Osteoporosis)
- Kidney bone disease (Osteodystrophy)

How Alfost works

Alfacalcidol 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.

Alfacalcidol is used to treat diseases where the amount of calcium in your body needs changing. It is used to treat:

- Changes in bone caused by kidney failure (osteodystrophy).
- Changes to your parathyroid glands. These are small glands found in your neck. They make a substance called the parathyroid hormone. This changes the amount of calcium in your body.
- The glands may make the amount of calcium in your blood too high. (hyperparathyroidism).

- The glands may make the amount of calcium in your blood too low (hypoparathyroidism).

Before you use Alfost

-When you must not take it

- If you are allergic (hypersensitive) to alfacalcidol or any of the other ingredients.
- If you know you have a condition called hypercalcaemia. This means you have high levels of calcium in your blood.
- If you know that you have a condition called calcification. This means you have high levels of calcium in your body tissues.

If you are pregnant, trying to get pregnant, or think you may be pregnant, consult your doctor before taking this medicine

If you are breastfeeding, consult your doctor before taking this medicine. If you are unsure if any of the above apply to you, talk to your doctor before taking alfacalcidol

-Before you start to take it

Talk to your doctor, pharmacist or nurse before taking Alfost

- If you are taking any of the medicines in the ‘Taking other medicines’ section below.
- If you have any problems with your kidneys. This includes if you have kidney stones.
- If you have granulomas or sarcoidosis. You may be more sensitive to Alfost. You may get too much calcium or phosphate in your blood when you take this medicine. Please read section ‘Side Effects’ 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 Alfost your doctor will take regular blood tests. This is very important in children, patients with kidney 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.
- Your doctor may prescribe another medicine called a

phosphate binding agent to take as well as Alfost. This will help to keep the right amount of phosphate in your blood.

- Your doctor may also prescribe a calcium supplement to take as well as Alfost. This is to maintain the right amount of calcium in your blood.

-Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes any medicines which you have bought without a prescription. You must tell your doctor or pharmacist if you are taking any of the following medicines:

- Anticonvulsants (for example, barbiturates, phenytoin, carbamazepine or primidone): for epilepsy or fits. You may need a larger dose of Alfost.
- 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.
- Calcium-containing medicines. You may get too much calcium in your blood.
- Other medicines that contain vitamin D. You may get too much calcium in your blood.
- Antacids containing magnesium: for heartburn or indigestion. You may get too much magnesium in your blood.
- Medicines containing aluminium. Too much aluminium is toxic.
- Bile acid sequestrants such as cholestyramine: for lowering your cholesterol level, or to help stop some types of diarrhoea or itching. Your Alfost may not enter your blood as usual.

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How to use Alfost

-How much to use

Always use alfacalcidol exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

-When to use Alfost

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. When the blood tests are normal you can start your medicine again. It is important that you only take half the dose you had before.

-How long to use it

Continue using Alfost for as long as your doctor recommends.

-If you forget to use it

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.

-If you use too much (overdose)

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.

While you are using Alfost

-Things you must do

You must tell your doctor/ pharmacist about any herbal/ OTC drugs/ special diet you are currently taking/ or undergoing any medication for other conditions. You must keep away all the medicines away from children

-Things you must not do

You must not exceed the recommended dosage

-Things to be careful of

Please tell your doctor if you are pregnant/ planning to get pregnant/ or breastfeeding

Side effects

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

Alfacalcidol can increase the levels of calcium in your blood (hypercalcaemia) and if you have poor kidney function, alfacalcidol may also cause an increase in phosphate in your blood (hyperphosphataemia)

Due to the high levels of calcium in your blood, you may experience fatigue, weakness, dizziness, headache, nausea, dry mouth, constipation, diarrhea, stomach discomfort or high pulse rate.

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 may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and disposal of Alfost

-Storage

Store at temperature not exceeding 30°C.

-Disposal

Medicines should not be thrown away in waste water or in household waste.

Please ask your pharmacist how to throw away any medicine you do not need anymore. If you do this you will help protect the environment.

Product description

-What it looks like?

Alfost 0.25 mcg: White opaque oval shape soft gelatin capsule containing clear transparent liquid

Alfost 0.5 mcg: Red opaque oval shape soft gelatin capsule containing clear transparent liquid

Alfost 1 mcg: Brown opaque oval shape soft gelatin capsule containing clear transparent liquid

Pack size:

Carton containing 10 blisters of 10 capsules each

-Ingredients

Active Ingredient:

Alfost 0.25mcg – 0.25mcg Alfacalcidol

Alfost 0.5mcg – 0.5mcg Alfacalcidol

Alfost 1 mcg – 1 mcg Alfacalcidol

Inactive Ingredients:

Vitamin E Acetate, Medium Chain Triglycerides, Gelatin 160 Bloom, Glycerol, Potassium Sorbate and purified water.

Colouring Agent:

Alfost 0.25mcg – Titanium Dioxide

Alfost 0.5mcg – Titanium Dioxide and Red Iron Oxide

Alfost 1 mcg – Black Iron oxide and Red Iron Oxide

-MAL number

Alfost 0.25mcg - MAL21066035XC

Alfost 0.5mcg - MAL21066036XC

Alfost 1 mcg - MAL21066037XC

Manufacturer

XL Laboratories Pvt. Ltd., Plot A-141, EPIP, RIICO Industrial Area, Neemrana, Alwar, Rajasthan, 301701 (India)

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Alfacalcidol Capsules

Product Registration Holder/

Importer Unimed Sdn Bhd
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52200 Kuala Lumpur.

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