



Package leaflet: Information for the patient
Alfacalcidol 0.25 microgram soft capsules
Alfacalcidol 0.5 microgram soft capsules
Alfacalcidol 1.0 microgram soft 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 of the 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 is and what it is used for
2. What you need to know before you take Alfacalcidol
3. How to take Alfacalcidol
4. Possible side effects
5. How to store Alfacalcidol
6. Contents of the pack and other information

1. What Alfacalcidol is and what it is used for

Alfacalcidol contains the active substance alfacalcidol.

Alfacalcidol 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.

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.
 - o The glands may make the amount of calcium in your blood too high. (hyperparathyroidism).
 - o The glands may make the amount of calcium in your blood too low (hypoparathyroidism).
- Softening and deformity of the bones due to lack of calcium (rickets or osteomalacia).

2. What you need to know before you take Alfacalcidol

Do not take Alfacalcidol:

- If you are allergic to alfacalcidol, arachis oil (peanut oil), soy 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 know that you have a condition called calcification. This means you have high levels of calcium in your body tissues.
- If you are unsure if any of the above apply to you, talk to your doctor before taking Alfacalcidol.

Warnings and precautions

Talk to your doctor or pharmacist before taking Alfacalcidol.

In particular, tell your doctor:

- If you are taking any of the medicines in the "Other medicines and Alfacalcidol" section below.
- If you have any problems with your kidneys. This includes if you have kidney stones.
- If you have a disease which leads to formation of clumps of inflammatory cells in various organs (granulomas or sarcoidosis). You may be more sensitive to Alfacalcidol.

You may get too much calcium or phosphate or creatinine 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 Alfacalcidol 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 creatinine, 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 Alfacalcidol. 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 Alfacalcidol. This is to maintain the right amount of calcium in your blood.

Other medicines and Alfacalcidol

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.

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

- Anticonvulsants (for epilepsy or fits). 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.
- 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.
- Medicines that contain calcium or other medicines that contain vitamin D. You may get too much calcium in your blood.
- Barbiturates (for sleeping disorders). You may need a larger dose of Alfacalcidol.
- Antacids (for heartburn) and laxatives (for relieving constipation) containing magnesium:
- You may get too much magnesium in your blood.
- Medicines containing aluminium. Too much aluminium is toxic.
- Bile acid sequestrants such as colestyramine (for lowering cholesterol levels or stopping some types of diarrhea or itching). Alfacalcidol may not enter your blood as usual.

Pregnancy and breast-feeding

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.

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 (for example dizziness and decrease alertness due to alfacalcidol.)

Alfacalcidol contains arachis oil (peanut oil), lecithin (soya lecithin), ethanol and sorbitol:

Alfacalcidol capsules contain arachis oil (peanut oil), lecithin (soya lecithin). If you are allergic to peanut or soya, do not use this medicine.

This medicine contains 10 mg sorbitol in each capsule.

Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.

This medicinal product contains 1 mg of alcohol (ethanol) per soft capsule, corresponding to 1% (w/w). The amount of alcohol (ethanol) in one soft capsule of this medicine is equivalent to less than 1 ml of beer or 1 ml of wine. The small amount of alcohol in this medicine has no noticeable effects.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Alfacalcidol

Always take this medicine exactly as your doctor or pharmacist 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



Dimension - 135 x 420 mm

Front Side

ARTWORK DETAIL LABEL

Product	ALFACALCIDOL CAPSULES - 0.25/0.5/1 mcg			
Buyer/Country	SPUK	Component	PACK INSERT	
Dimension	135 x 420	Pack	----	
New Item Code	1048844	Old Item Code	1038087	
Colour Shades	BLACK	No. of Colours	1	
Change Control No.	PC-TSG/2023/020 - Record # 373751		Artwork Version	6.0
Design/Style	Front & Back side printing. To be supplied in the unfolded size.			
Substrate	60 GSM Paper.			
Special Instructions	PRINTING CLARITY TO BE CLEAR AND SHARP.			
Autocartonator Requirements	Pack insert supply should be as per auto-cartonator. Refer auto-cartonator drawing for instructions.			

Caution to the printer: Before processing, please ensure that the ARTWORK received for printing is exactly in line with APPROVED ARTWORK provided to you. In case of any FONTS/DESIGN are Mis-matching with the APPROVED ARTWORK, please inform PDC for further action. **DO NOT MAKE ANY CHANGE TO THE ARTWORK WITHOUT WRITTEN INSTRUCTIONS FROM PDC.**

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 you can start your medicine again. It is important that you only take half the dose you had before.

Adults and adolescents

The usual starting dose is 1 microgram each day. People usually take between 1 and 3 micrograms 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 prescribe another medicine called a calcium supplement to take as well as Alfacalcidol. This will help to keep the right amount of calcium level in your blood.

Elderly

The usual starting dose is 0.5 microgram each day.

Use in children

The dose depends on the weight of the child for children less than 20kg (called bodyweight).

- Children from 6 years of age and weighing less than 20 kilograms:

The usual starting dose is 0.05 microgram per kilogram bodyweight each day.

- Children weighing 20 kilograms and more:

The usual starting dose is 1 microgram each day.

If you take more Alfacalcidol 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

If you forget to take your medicine, take it as soon as you remember. Then take the next dose at the usual time. Do not take a double dose to make up for the forgotten one.

If you have any further questions on the use of this medicine, 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.

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. The frequency of these side effects is common (may affect up to 1 in 10 people):

- You feel weak or have pain in your muscles or bones
- You have lost weight
- You need to pass water (urine) more often
- You feel thirsty
- You feel fatigue
- You feel sick, vomit, have constipation or diarrhoea
- You have lost your appetite
- You are sweating a lot
- You are having headaches
- You feel confused
- You feel drowsy
- You have high blood pressure
- You have a metallic taste in your mouth

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 not known (cannot be estimated from the available data):

- 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 (may affect up to 1 in 10 people):

- High levels of calcium in the urine or blood

- High levels of phosphate in the blood
- Abdominal/stomach pain or discomfort
- Rash
- Itching

Uncommon (may affect up to 1 in 100 people):

- Headache
- Diarrhoea, vomiting, constipation, nausea
- Muscle pain
- Fatigue
- Deposits of calcium in the body (calcinosis)
- Feeling weak or unwell
- Increased calcium levels in the kidneys, kidney stones
- Confusion
- Renal impairment (including acute renal failure)

Rare (may affect up to 1 in 1,000 people):

- Dizziness

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 Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store alfacalcidol

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date on the carton. 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 medicine via waste water or household waste. Please 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 contains

The active substance is alfacalcidol.

Each Alfacalcidol 0.25 microgram soft capsule contains 0.25 microgram of alfacalcidol.

Each Alfacalcidol 0.5 microgram soft capsule contains 0.5 microgram of alfacalcidol.

Each Alfacalcidol 1.0 microgram soft capsules contains 1 microgram of alfacalcidol.

The other ingredients are:

- citric acid, anhydrous;
- all-rac- α -Tocopherol;
- propyl gallate;
- ethanol, anhydrous;
- arachis oil, hydrogenated.

The capsule shell contains

- gelatin;
- glycerol;
- anidrisorb;
- purified water;
- medium chain triglyceride
- soya lecithin.

The capsules contain the following colours: 0.25 microgram capsules: titanium dioxide (E171), ferric oxide red (E172) and ferric oxide black (E172)

0.5 microgram capsules: titanium dioxide (E171) and ferric oxide red (E172)

1.0 microgram capsules: titanium dioxide (E171) and ferric oxide yellow (E172)

What Alfacalcidol looks like and contents of the pack

Alfacalcidol 0.25 mcg capsule: reddish brown colored, oval shaped soft gelatin capsules containing clear oily liquid.

Alfacalcidol 0.5 mcg capsule: light pink colored, oval shaped soft gelatin capsules containing clear oily liquid.

Alfacalcidol 1.0 mcg capsule: pale yellow colored, oval shaped soft gelatin capsules containing clear oily liquid.

Alfacalcidol comes in white opaque HDPE container, with white opaque HDPE screw closure and induction sealing in a pack of 30 capsules, 50 capsules and 100 capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Strides Pharma UK Ltd.
Unit 4, The Metro Centre,
Dwight Road, Watford,
WD18 9SS
United Kingdom

This leaflet was last revised in 09/2023.



10462



10462

1048844



Z9P01

Dimension - 135 x 420 mm

Back Side

ARTWORK DETAIL LABEL

Product	ALFACALCIDOL CAPSULES - 0.25/0.5/1 mcg				
Buyer/Country	SPUK	Component	PACK INSERT		
Dimension	135 x 420			Pack	----
New Item Code	1048844	Old Item Code	1038087		
Colour Shades	BLACK			No. of Colours	1
Change Control No.	PC-TSG/2023/020 - Record # 373751			Artwork Version	6.0
Design/Style	Front & Back side printing. To be supplied in the unfolded size.				
Substrate	60 GSM Paper.				
Special Instructions	PRINTING CLARITY TO BE CLEAR AND SHARP.				
Autocartonator Requirements	Pack insert supply should be as per auto-cartonator. Refer auto-cartonator drawing for instructions.				
Caution to the printer: Before processing, please ensure that the ARTWORK received for printing is exactly in line with APPROVED ARTWORK provided to you. In case of any FONTS/DESIGN are Mis-matching with the APPROVED ARTWORK, please inform PDC for further action. DO NOT MAKE ANY CHANGE TO THE ARTWORK WITHOUT WRITTEN INSTRUCTIONS FROM PDC.					