



# Alfacalcidol

- 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.

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

- 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).

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.

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



Front Side

### ARTWORK DETAIL LABEL

|                      |                                               |               |             |                |       |
|----------------------|-----------------------------------------------|---------------|-------------|----------------|-------|
| <b>Product</b>       | <b>ALFACALCIDOL CAPSULES - 0.25/0.5/1 mcg</b> |               |             |                |       |
| <b>Buyer/Country</b> | SPUK                                          | Component     | PACK INSERT |                |       |
| <b>Dimension</b>     | 135 x 420                                     |               |             | Pack           | ----- |
| <b>New Item Code</b> | 1048844                                       | Old Item Code | 1038087     |                |       |
| <b>Colour Shades</b> | 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 | <b>Pack insert supply should be as per auto-cartonator. Refer auto-cartonator drawing for instructions.</b> |                 |     |

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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](http://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- $\alpha$ -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.**



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Dimension - 135 x 420 mm

Back Side

| ARTWORK DETAIL LABEL                                                                                                                                                                                                                                                                                                                                               |                                                                                                      |               |             |                 |      |
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RD/PD/003/F-08/R0