

**Alpha D₃ 0.25 mcg, Alpha D₃ 0.5 mcg, Alpha D₃ 1.0 mcg
Soft gelatin capsules**

Active ingredient

Each soft gelatin capsule of Alpha D₃ 0.25 mcg contains alfacalcidol 0.25 mcg

Each soft gelatin capsule of Alpha D₃ 0.5 mcg contains alfacalcidol 0.5 mcg

Each soft gelatin capsule of Alpha D₃ 1.0 mcg contains alfacalcidol 1 mcg

For inactive ingredients and allergens in this medicine, see section 2 under 'Important information about some of this medicine's ingredients', and section 6 'Additional information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist. This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar to yours.

1. What is this medicine intended for?

Alpha D₃ is intended for the treatment of a bone disease related to a kidney function disorder (renal bone disease [renal osteodystrophy]), hypoparathyroidism, primary and tertiary hyperparathyroidism (including bone disease), rickets and osteomalacia and osteoporosis.

Therapeutic group: Vitamin D and analogues.

2. Before using this medicine

Do not use this medicine if:

- You are sensitive (allergic) to alfacalcidol, other vitamin D products or to any of the other ingredients this medicine contains (see section 6 'Additional information').
- You are sensitive (allergic) to peanuts or soya. These capsules contain small quantities of peanut oil (arachis oil), which may cause a severe allergic reaction in people who are sensitive to it.
- You have a condition called hypercalcemia, in which the levels of calcium in the blood are high.
- You have a condition called calcification, in which the levels of calcium in body tissues are high.

Special warnings about using this medicine

Before treatment with Alpha D₃, tell your doctor if:

- you are taking any of the medicines mentioned in the 'Interactions with other medicines' section below in this leaflet.
- you have kidney problems (including kidney stones).
- you have a disease which leads to the formation of clumps of inflammatory cells in various organs (granulomas or sarcoidosis). You may be more sensitive to Alpha D₃.
- you have an intolerance to some sugars, as this medicine contains a small amount of sorbitol.
- you follow a low-calcium diet, as it may harm the effectiveness of the medicine.

You may develop high levels of calcium or phosphate in your blood when taking this medicine. (See section 4 'Side effects' so you can identify signs of this effect). Notify your doctor of this. Your doctor may need to change your dose.

During treatment with Alpha D₃, and depending on the results of your blood tests, your doctor may also prescribe you:

- A medicine that binds to phosphate in order to maintain the right level of phosphate in your blood.
- A calcium supplement in order to maintain the right level of calcium in your blood.

Children and adolescents

This medicine is not intended for children who weigh less than 20 kg.

Tests and follow-up

While you are being treated with this medicine, your doctor will take regular blood tests. This is particularly important in children, patients with kidney problems, and patients on a high dose of Alpha D₃. This is to monitor the level of calcium and phosphate in your blood while you are being treated with the medicine. Depending on your blood test results, the dosage will be adjusted for you in order to achieve the desired response.

Interactions with other medicines

If you are taking or have recently taken other medicines, including nonprescription medicines and dietary supplements, tell your doctor or pharmacist.

Particularly if you are taking:

- cardiac glycosides (for heart problems), e.g. digoxin, as the level of calcium in your blood may increase, and this could result in an abnormal heartbeat.
- barbiturates (to treat anxiety and insomnia), e.g. phenobarbital, as you may need a larger dose of Alpha D₃.
- anticonvulsants (to treat epilepsy or fits), e.g. phenytoin, carbamazepine or primidone, as you may need to increase the dose of Alpha D₃.
- mineral oil (to relieve constipation), as it affects the absorption of Alpha D₃ into the blood.
- colestyramine or colestipol (to lower cholesterol levels), as they affect the absorption of Alpha D₃ into the blood.
- sucralfate (to treat and prevent gastric ulcers), as it affects the absorption of Alpha D₃ into the blood.
- large amounts of aluminium-containing antacids (to relieve heartburn and indigestion) e.g. aluminium hydroxide, as a large quantity of aluminium is toxic.
- magnesium-containing antacids (to relieve heartburn or indigestion) or laxatives (to treat constipation) that contain magnesium hydroxide, as the amount of magnesium in your blood may be too high.
- products containing calcium (to treat calcium deficiency) e.g. calcium gluconate, as the amount of calcium in your blood may be too high.
- thiazide diuretics (for increasing the amount of urine the body produces) e.g. bendroflumethiazide, as the amount of calcium in your blood may be too high.
- other medicines containing vitamin D (to treat bone disease), e.g. ergocalciferol, as the amount of calcium in the blood may be too high.

Using this medicine and food

Do not chew! Swallow the capsules with a little water.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to become pregnant, consult your doctor before using this medicine.

Driving and using machines

Alpha D₃ is not expected to affect your ability to drive or operate machines. Consult your doctor if you experience any side effect from Alpha D₃ that you feel may affect your ability to drive and/or operate machines (e.g., dizziness or decreased alertness).

Important information about some of this medicine's ingredients

- Alpha D₃ contains arachis oil (peanut oil). **If you are allergic to peanuts or soya, do not use this medicine.**
- Alpha D₃ contains small amounts of ethanol (alcohol) (less than 2 mg per capsule). The amount of alcohol (ethanol) in one soft gelatin capsule of this medicine is equivalent to less than 1 mL of beer or wine. The small amount of alcohol in this medicine has no marked effect.
- Alpha D₃ contains a small amount (up to 3.16 mg per capsule) of sorbitol. If you have been told by your doctor that you have an intolerance to some sugars, consult your doctor before taking this medicine.

3. How to use this medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dosage or about how to take this medicine. Only your doctor will determine your dosage and how you should take this medicine. The recommended dosage is usually:

For bone disease related to kidney problems, rickets, osteomalacia and parathyroid problems

- **Adults and children over 20 kg** - 1.0 mcg a day
- **The elderly** - 0.5 mcg a day

For osteoporosis

- **Adults (including the elderly)** - 0.5 mcg a day

Do not exceed the recommended dose.

If you have accidentally taken a higher dose or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

An overdose is likely to cause lack of appetite, general weakness, feeling sick, being sick, weakness, sweating, diarrhoea, headache, weight loss, vertigo, thirst and excessive urination.

If you forget to take the medicine

Take the dose as soon as you remember, unless it is almost time to take the next dose. Do not take a double dose to make up for the forgotten dose. Take the next doses at the regular time.

Adhere to the treatment as recommended by your doctor.

If you stop taking this medicine

Even if your health improves, do not stop taking this medicine without consulting your doctor.

Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

Like with all medicines, using Alpha D₃ may cause side effects in some users. Do not be alarmed by this list of side effects. You may not experience any of them.

The side effects are generally caused by excess calcium in the blood.

Stop the treatment and go to your doctor or the nearest hospital immediately if you experience the following symptoms of a severe allergic reaction:

- swelling of the lips, face or neck/throat
- severe difficulty breathing due to swelling of the neck/throat
- severe rash or hives (urticaria)

These are very rare, but very serious side effects. You may need urgent medical attention or hospitalisation.

Contact your doctor immediately if you notice any of the following side effects, as this could indicate that you have too much calcium or phosphate in your blood. These side effects may affect up to 1 in 10 patients:

- feeling or being sick
- general weakness and lack of energy
- lack of appetite
- increased thirst
- unexpected weight loss
- increased sweating
- vertigo (feeling that you, or things around you, are moving when they are not)
- headaches
- excessive urination
- dry mouth or a metallic taste in your mouth
- muscle or bone pain
- constipation or diarrhoea

Contact your doctor as soon as possible if you experience any of the following as this could indicate that you are developing kidney problems such as formation of kidney stones. Kidney stones can cause a sharp spasm on one side of your lower back. The frequency of this side effect is unknown (cannot be estimated from the existing information):

- less frequent urination
- swelling of various parts of your body (oedema)
- fever with a pain on the side of your body

Other possible side effects of unknown frequency (cannot be estimated from the existing information):

- hives (urticaria)

Other possible side effects that may affect up to 1 in 10 patients, including skin problems such as:

- itching skin
- rash

Other possible side effects that may affect up to 1 in 100 patients, including:

Development of calcium deposits in your kidneys (nephrocalcinosis) or other part of your body (calcification of soft tissues)

If you experience any side effect, if any side effect gets worse or if you experience a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects

You can report side effects to the Ministry of Health by following the 'Reporting Side Effects of Drug Treatment' link on the Ministry of Health home page (www.health.gov.il), which opens an online form for reporting side effects, or you can also use this link: <https://sideeffects.health.gov.il>

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this and all other medicines in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- Store in a dark place, below 25°C.
- Do not throw away medicines via wastewater or household waste. Ask the pharmacist how to throw away medicines that you no longer use. These measures will help protect the environment.

6. Additional information

In addition to the active ingredient, this medicine also contains:

Alpha D₃ 0.25 mcg capsules

Inactive ingredients:

Arachis oil, ethanol dehydrated, propyl gallate, vitamin E (dl-alpha-tocopherol), citric acid anhydrous.

Soft capsule shell:

Gelatin, glycerol 85%, anidrisorb 85/70 (sorbitol, mannitol, sorbitan, hydrogenation products of partly hydrolyzed starch, water), red iron oxide (E172), edible ink black, purified water.

Alpha D₃ 0.5 mcg capsules

Inactive ingredients:

Arachis oil, ethanol dehydrated, propyl gallate, vitamin E (dl-alpha-tocopherol), citric acid anhydrous.

Soft capsule shell:

Gelatin, glycerol 85%, anidrisorb 85/70 (sorbitol, mannitol, sorbitan, hydrogenation products of partly hydrolyzed starch, water), titanium dioxide (E171), red iron oxide (E172), edible ink black, purified water.

Alpha D₃ 1.0 mcg capsules

Inactive ingredients:

Arachis oil, ethanol dehydrated, propyl gallate, vitamin E (dl-alpha tocopherol), citric acid anhydrous.

Soft capsule shell:

Gelatin, glycerol 85%, anidrisorb 85/70 (sorbitol, mannitol, sorbitan, hydrogenation products of partly hydrolyzed starch, water), titanium dioxide (E171), yellow iron oxide (E172), edible ink black, purified water.

What the medicine looks like and contents of the pack:

Alpha D₃ 0.25 mcg

Oval, opaque, reddish-brown, elastic soft gelatin capsule containing a clear pale-yellow oily solution. On one side, "0.25" is printed in black ink.

Contents of the pack: 10, 20, 30, 40, 50, 60 or 100 capsules.

Alpha D₃ 0.5 mcg

Oval, opaque, pale pink, elastic soft gelatin capsule containing a clear pale-yellow oily solution. On one side, "0.5" is printed in black ink.

Contents of the pack: 10, 30 or 100 capsules.

Alpha D₃ 1.0 mcg

Oval, opaque, cream-to-ivory, elastic soft gelatin capsule containing a clear pale-yellow oily solution. On one side, "1.0" is printed in black ink.

Contents of the pack: 10, 20, 30, 40, 50, 60 or 100 capsules.

Not all pack sizes may be marketed.

Registration holder's name and address:

Truemed Ltd., 10 Beni Gaon St., Poleg Industrial Park, P.O. Box 8105, Netanya 4250499.

Manufacturer's name and address:

Theramex Ireland Limited, Dublin, Ireland.

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Registration number of the medicine in the Ministry of Health's National Drug Registry:

Alpha D₃ 0.25 mcg capsules: 125 64 30474

Alpha D₃ 0.5 mcg capsules: 122 51 30212

Alpha D₃ 1.0 mcg capsules: 125 65 30475

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