

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

Alpha D₃ 0.25 mcg

Alpha D₃ 0.5 mcg

Alpha D₃ 1.0 mcg

Capsules

Active ingredient

Each soft gelatin capsule contains:

Alfacalcidol 0.25 mcg, 0.5 mcg or 1 mcg (1α hydroxyvitamin D₃)

For the inactive and allergenic ingredients in the medicine, see section 2 under "Important information about some of the ingredients of the medicine" and section 6 "Further Information".

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for the treatment of your ailment. Do not pass it on to others. It may harm them, even if it seems to you that their ailment is similar.

The medicine contains a number of ingredients that may cause allergy in people sensitive to them; carefully read the warnings in section 2.

1. WHAT IS THE MEDICINE INTENDED FOR?

Alpha D₃ is intended to treat bone disease related to kidney problems (renal bone disease [renal osteodystrophy]), rickets and osteomalacia, hypoparathyroidism, primary and tertiary hyperparathyroidism (including bone disease) and osteoporosis.

Therapeutic group: Vitamin D and analogs.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You are sensitive (allergic) to alfacalcidol, to vitamin D or its derivatives or to any of the additional ingredients contained in the medicine (see section 6 "Further Information").
- You are sensitive (allergic) to peanuts or soya. The medicine contains a small amount of peanut oil (arachis oil), which can cause a severe allergic reaction in people sensitive to these ingredients.
- You suffer from high levels of calcium in the blood (hypercalcemia).
- You suffer from calcification (a condition in which you have high levels of calcium in the body tissues).

Special warnings regarding use of the medicine

Before treatment with Alpha D₃, tell your doctor if:

- You suffer from kidney problems (including kidney stones).
- You are on a low-calcium diet (may impair the effectiveness of the medicine).
- You may develop high levels of calcium or phosphate in your blood during use of the medicine (see section 4 "Side Effects" to detect signs of this effect). Notify the doctor. The doctor will consider changing your dosing regimen.
- During the course of treatment with Alpha D₃, the doctor will consider prescribing another phosphate-binding medicine to maintain an appropriate level of phosphate in your blood.

Children

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

Tests and follow-up

During the course of treatment with this medicine, the doctor will perform regular blood tests for you. These tests are especially important in children, in patients with kidney problems, or in patients treated with a high dosage of Alpha D₃. These tests are to monitor the levels of calcium and phosphate in your blood during the course of treatment with this medicine.

Drug interactions

If you are taking, or if you have recently taken, other medicines including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.

Especially if you are taking or planning to take:

- Cardiac glycosides (for heart problems), e.g., digoxin.
- Barbiturates (to treat anxiety and insomnia), e.g., phenobarbital.
- Antiepileptics (to treat epilepsy and fits), e.g., phenytoin, carbamazepine, primidone.
- Mineral oil (to relieve constipation).
- Cholestyramine, colestipol (to reduce cholesterol levels).
- Sucralfate (to treat and prevent gastric ulcer).
- Large amount of aluminum-containing antacids (to treat heartburn and indigestion), e.g., aluminum hydroxide.
- Magnesium-containing antacids (to relieve heartburn and indigestion) or laxatives (to treat constipation), e.g., magnesium hydroxide.
- Other preparations containing calcium (to treat calcium deficiency), e.g., calcium gluconate.
- Thiazide diuretics (used to increase the amount of urine your body generates), e.g., bendroflumethiazide.
- Other medicines containing vitamin D (to treat bone diseases), e.g., ergocalciferol.

Pregnancy and breastfeeding

If you are pregnant, think you are pregnant or planning to become pregnant, consult the doctor regarding use of the medicine. Consult the doctor if you are breastfeeding.

Important information about some of the ingredients of the medicine

- Alpha D₃ contains peanut oil (arachis oil). **If you are allergic to peanuts or soya, do not take the medicine.**
- Alpha D₃ contains a small amount of sorbitol. If the doctor has told you that you have an intolerance to certain sugars, consult the doctor before taking this medicine.
- Alpha D₃ contains mannitol, which may cause diarrhea.

Driving and operating machinery

Your ability to drive or operate machinery is not expected to be affected while using this medicine.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the medicine. The dosage and treatment regimen will be determined by the doctor only.

To determine the proper dosage for you, blood tests should be performed regularly in order to monitor calcium and phosphate levels in your blood (especially if you suffer from kidney problems).

Do not exceed the recommended dose.

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

If you accidentally took a higher dosage or if a child has accidentally swallowed the medicine, immediately refer to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you. A higher dosage than recommended may cause lack of appetite, generalized weakness, nausea, vomiting, weakness, sweating, diarrhea, headache, weight loss, dizziness (vertigo), thirst and excessive urination.

If you forgot to take the medicine at the required time, take the dose as soon as you remember, unless it is nearly time for the next dose. Do not take a double dose to compensate for the forgotten dose. Afterwards, take the next dose at the usual time.

Adhere to the treatment regimen as recommended by the doctor.

If you stop taking the medicine

Even if there is an improvement in your health, do not stop treatment without consulting the doctor.

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

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Alpha D₃ may cause side effects in some users.

Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Stop treatment and immediately refer to a doctor or proceed to the nearest hospital in cases of the following allergic reactions:

- Swelling of the lips, face or neck leading to severe difficulty in breathing.
- Rash or hives (urticaria).

These are very serious but rare effects. You may need urgent medical attention or hospitalization.

Refer to a doctor immediately if you notice one of the following effects:

- Nausea, vomiting or diarrhea.
- Generalized weakness and lack of energy, lack of appetite, thirst, weight loss.
- Sweating.
- Dizziness (vertigo).
- Headache.
- Excessive urination.
- Dry mouth or a metallic taste in your mouth.
- Pain in muscles or bones.
- Constipation.

Other possible side effects:

- Skin effects, such as:
 - Skin itchiness.
 - Rash.
- Itchy skin rash, that appears in the form of red bruises (urticaria).

Effects indicating kidney problems, with symptoms such as:

- Decreased frequency of urination.
- Swelling of different parts of the body.
- Fever accompanied by pain on the side of the body.

Effects indicating a metabolic and nutritional problem:

- High calcium level in the blood (hypercalcemia).
- Disturbance in electrolyte balance with increased level of phosphate in the blood (hyperphosphatemia).

These symptoms are signs that may indicate that kidney problems are developing, such as formation of kidney stones. Kidney stones may cause a sharp spasm in one side of the lower back.

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:

<https://sideeffects.health.gov.il>

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine must be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.

- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.

- **Store in a dark place, below 25°C.**

- Do not discard medicines via wastewater or the waste bin. Ask the pharmacist how to dispose of medicines that are not in use. These measures will help protect the environment.

6. FURTHER INFORMATION

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

Alpha D₃ 0.25 mcg capsules

Filling:

Arachis oil, dehydrated alcohol, propyl gallate, dl-alpha-tocopherol, citric acid anhydrous.

Soft Gelatin Capsule Shell:

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

Alpha D₃ 0.5 mcg capsules

Filling:

Arachis oil, dehydrated alcohol, propyl gallate, dl-alpha-tocopherol, citric acid anhydrous.

Soft Gelatin 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), printing ink black, purified water.

Alpha D₃ 1.0 mcg capsules

Filling:

Arachis oil, dehydrated alcohol, propyl gallate, dl-alpha tocopherol, citric acid anhydrous.

Soft Gelatin 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), printing ink black, purified water.

What the medicine looks like and contents of the pack:

Alpha D₃ 0.25 mcg capsules

An oval, opaque, reddish-brown, soft gelatin capsule, imprinted on one side with "0.25" in black ink and containing a pale yellow, clear oily solution.

Package content: 10, 20, 30, 40, 50, 60 or 100 capsules (not all package sizes may be marketed).

Alpha D₃ 0.5 mcg capsules

An oval, opaque, light pink, soft gelatin capsule, imprinted on one side with "0.5" in black ink and containing a pale yellow, clear oily solution.

Package content: 10, 30 or 100 capsules (not all package sizes may be marketed).

Alpha D₃ 1.0 mcg capsules

An oval, opaque, cream-ivory, soft gelatin capsule, imprinted on one side with "1.0" in black ink and containing a pale yellow, clear oily solution.

Package content: 10, 20, 30, 40, 50, 60 or 100 capsules (not all package sizes may be marketed).

Name of Manufacturer and its Address: Theramex, Dublin, Ireland.

Registration Holder and its Address: Truemed Ltd., 10 Beni Gaon St., Netanya 4250499.

Revised in January 2022 according to MOH guidelines.

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

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