

ONE-ALPHA[®] CAPSULE

Alfacalcidol (0.25mcg, 0.5mcg, 1mcg)

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What One-Alpha[®] Capsule is used for and how One-Alpha[®] Capsule works

It contains alfacalcidol, which is a vitamin D-like substance that promotes the absorption of calcium and phosphate in food from the intestines. If you have imbalance in the body's calcium conversion, you can take One-Alpha[®] Capsule to prevent changes in your bone structure.

Your doctor may have prescribed another use. Always follow the doctor's instructions.

Before you take One-Alpha[®] Capsule

- When you must not take it

Do not take One-Alpha[®] Capsule if you have too much calcium in your blood (hypercalcaemia), or you are hypersensitive to alfacalcidol or any of the other excipients. One-Alpha[®] Capsules contain sesame oil, which in rare cases may cause severe allergic reactions.

- Before you start to take it

When you are receiving treatment with One-Alpha[®] Capsule, you must have your kidneys and the levels of calcium and phosphorus in your blood monitored frequently.

If you take diuretic medicine (thiazide) or medicine that contains

calcium, there is a risk that the calcium level in your blood becomes too high. Consult your doctor.

If you have reduced kidney function, you should take a phosphate binding medicine together with One-Alpha[®] Capsule. Consult your doctor.

- Taking other medicine

Always inform your doctor or pharmacist if you are taking other medication or have done so recently. This also applies to non-prescription medicine, medicine purchased abroad, homeopathic remedies or strong vitamins and minerals.

Consult your doctor if you take medicine for epilepsy (phenytoin or phenobarbital). You may need a larger dose of One-Alpha[®] Capsule.

Inform your doctor if you take heart medicine (digoxin). There may be a risk of heart problems if you get too much calcium in your blood when you One-Alpha[®] Capsule.

How to take One-Alpha[®] Capsule

- How much to take

Adults and children over 20 kg:

One Alpha[®] Capsule 0.25mcg:

You start by taking 4 capsules (1 microgram) daily.

One Alpha[®] Capsule 0.5mcg:

You start by taking 2 capsules (1 microgram) daily.

One Alpha[®] Capsule 1mcg:

You start by taking 1 capsule daily.

Thereafter the dose is adjusted to suit your needs.

The dose will usually lie between 0.25 and 2 micrograms daily. It is essential that the level of calcium in the blood is monitored by blood tests. Consult your doctor.

Children (> 1 month) under 20 kg:
The initial dose is 0.05 microgram/kg body weight daily.

One Alpha[®] Capsule 0.25mcg:

For example, a child weighing 10 kg will have an initial dose of 0.5 micrograms (2 capsules) daily.

One Alpha[®] Capsule 0.5mcg:

For example, a child weighing 10 kg will have an initial dose of 0.5 micrograms (1 capsule) daily

One Alpha[®] Capsule 1mcg:

For example, a child weighing 10 kg will have an initial dose of 0.5 micrograms daily.

Thereafter the dose will be adjusted by the doctor so that it suits the needs of the child.

Neonates: 0.1 microgram/kg/day

- When to take it

The capsules should be taken with a glass of water and swallowed whole. You can take One-Alpha[®] Capsule together with food and beverages.

Always follow the doctor's instructions. Not all patients have the same requirements. You should only change the dose or stop the treatment according to the doctor's advice.

- If you forget to take it

If you have forgotten to take One-Alpha[®] Capsule, do not take a double dose; just continue with the normal dose.

- If you take too much (overdose)

Contact your doctor if you have taken more One-Alpha[®] Capsule than prescribed by your doctor. There may be a risk of increased calcium in the blood. This can cause serious side effects. The symptoms of overdose are the same as described under Side effects.

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While you are taking it

- Things to be careful of

Pregnancy and lactation

Get advice from your doctor or pharmacist before you take any form of medicine.

Pregnancy: You should only take One-Alpha[®] Capsule according to doctor's instructions.

Breastfeeding: You should only take One-Alpha[®] Capsule according to doctor's instructions.

Side effects

Like all medicines, One-Alpha[®] Capsule may cause side effects. The side effects are due to symptoms of too much calcium in the blood. Contact your doctor immediately if you suspect side effects. Frequent checks by the doctor and monitoring of blood tests prevent side effects.

Serious side effects

Very rare side effect (occurs in less than 1 in 10,000 treated):

Coma (deep unconsciousness), acute infection in the pancreas (severe stomach pains and fever). Contact your doctor or the emergency room if necessary.

Calcium deposits in the sclera and conjunctiva in the eye.

Frequency unknown:

Irregular heartbeat, calcification in the kidneys, kidney failure, cessation of growth in children.

Non-serious side effects

Frequent side effects (occurs in more than 1 in 10 treated):

Increased level of calcium in the blood (hypercalcaemia).

Normal side effects (occurs in between 1 and 10 of 100 treated):

Increased content of urea in the blood.

Rare side effects (occurs in between 1 and 10 of 1000 treated):

High blood pressure.

Very rare side effects (occurs in less than 1 in 10,000 treated):

Restlessness and confusion, hallucinations, lethargy, rash with red spots, psoriasis.

The following side effects may also occur:

Loss of appetite, weight loss, thirst, dehydration, nausea and vomiting, constipation, stomach ache/cramps, dry mouth, metallic taste, headache, fever, exhaustion, extreme tiredness, sensory disturbances, photosensitivity, cold, itchy skin, nettle fever, rash, muscle and bone aches, calcification in the muscles and connective tissue, frequent urination, nocturia, infection in the urinary tract, reduced libido, albumin in the urine, high cholesterol in the blood, increased liver count.

Inform your doctor or pharmacist if you have any side effects which persist or are irritating. Some side effects may require treatment.

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

Storage and disposal of One-Alpha[®] Capsule

- Storage

One-Alpha[®] Capsule must be stored out of reach of children and store below 30°C, protect from direct sunlight.

Do not take One-Alpha[®] Capsule after the expiry date, printed on the package.

- Disposal

Always return unused medicine to the pharmacist.

Product Description

- What it looks like

One-Alpha[®] Capsule 0.25mcg is a cream coloured capsule.

One-Alpha[®] Capsule 0.5mcg is a reddish-coloured (pink) capsule.

One-Alpha[®] Capsule 1mcg is a brownish-coloured capsule.

- Ingredients

One-Alpha[®] Capsules 0.25mcg:

- Active ingredient: Alfacalcidol
- Inactive ingredients: Sesame oil, all-rac- α -tocopherol, gelatine, glycerol, potassium sorbate, titanium dioxide (E 171).

One-Alpha[®] Capsules 0.5 mcg:

- Active ingredient: Alfacalcidol
- Inactive ingredients: Sesame oil, all-rac- α -tocopherol, gelatine, glycerol, potassium sorbate (E202), titanium dioxide (E 171), red iron dioxide (E172).

One-Alpha[®] Capsules 1mcg:

- Active ingredient: Alfacalcidol
- Inactive ingredients: Sesame oil, all-rac- α -tocopherol, gelatine, glycerol, potassium sorbate, black iron dioxide (E 172), red iron dioxide (E172).

- MAL number:

One-Alpha[®] Capsules 0.25mcg: MAL19913218X

One-Alpha[®] Capsule 0.5 mcg: MAL20002463X

One-Alpha[®] Capsule 1mcg: MAL19913217X

ONE-ALPHA[®] CAPSULE

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Manufacturer

LEO Pharma A/S, 55, Industriparken,
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Product Registration Holder

DKSH Malaysia Sdn Bhd
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