

Package leaflet: Information for the user
One-Alpha® 2 micrograms/ml oral drops

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, pharmacist or nurse.
- 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 side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- In this leaflet One-Alpha oral drops will be called One-Alpha.

What is in this leaflet:

1. What One-Alpha® is and what it is used for
2. What you need to know before you take One-Alpha®
3. How to take One-Alpha®
4. Possible side effects
5. How to store One-Alpha®
6. Contents of the pack and other information

1. What One-Alpha® is and what it is used for

One-Alpha contains the active substance alfacalcidol. One-Alpha 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.

One-Alpha 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.

One-Alpha is used to treat diseases where the amount of calcium in your body needs to be changed. 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.
 - °The glands may make the amount of calcium in your blood too high (hyperparathyroidism).
 - °The glands may make the amount of calcium in your blood too low (hypoparathyroidism).
- Low levels of calcium in the blood of newborn babies (hypocalcaemia).
- Softening and deformity of the bones due to lack of calcium (rickets or osteomalacia).

2. What you need to know before you take One-Alpha®

Do not take One-Alpha

- If you are allergic (hypersensitive) to alfacalcidol or any of the other ingredients. You can find a list of these ingredients in section 6 of this leaflet.
- 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 One-Alpha.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking One-Alpha:

- If you are taking any of the medicines in the "Other medicines and One-Alpha" section below.
- If you have any problems with your kidneys. This includes if you have kidney stones.
- If you know that you have any sugar intolerance. You may have inherited this condition from someone else in your family.
- If you have granulomas or sarcoidosis. You may be more sensitive to alfacalcidol.

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 may need to change your dose.

While you are taking One-Alpha 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 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 One-Alpha. 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 One-Alpha. This will help to keep the right amount of calcium in your blood.

Other medicines and One-Alpha

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.

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

- Anticonvulsants (for example, barbiturates, phenytoin, carbamazepine or primidone): for epilepsy or fits. You may need a larger dose of One-Alpha.
- 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.
- Calcium-containing medicines. You may get too much calcium in your blood.
- Other medicines that contain vitamin D. You may get too much calcium in your blood.
- Antacids containing magnesium: for heartburn or indigestion. You may get too much magnesium in your blood.
- Medicines containing aluminium. Too much aluminium is toxic.
- Bile acid sequestrants such as cholestyramine: for lowering your cholesterol level, or to help stop some types of diarrhoea or itching. Your One-Alpha 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, for example dizziness, that may stop you from driving or using machines.

Important information about some of the ingredients in One-Alpha

One-Alpha contains:

- Ethanol. This is an alcohol. This medicine contains up to 340 mg per dose (corresponding to 6 micrograms of alfacalcidol), which is equivalent to 14 vol%. The amount of ethanol in each dose of One-Alpha is equivalent to less than 9 ml beer or 4.5 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects. The alcohol content may need to be taken into account for young children.
- Methylparahydroxybenzoate (E218). May cause allergic reactions (possibly delayed). Please read section 4 of this leaflet so you can spot any signs this may be happening to you.
- Macrogolglycerol hydroxystearate. May cause a stomach upset or diarrhoea.
- Sorbitol (E420). One-Alpha oral drops contain 452 mg sorbitol in each ml. 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.
- Sodium. This medicine contains less than 1 mmol sodium (23 mg) per ml, that is to say essentially 'sodium free'.

Please ask your doctor if you are worried about any of the ingredients in this medicine.

3. How to take One-Alpha®

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

How to measure a drop

Do not shake the bottle. Unscrew the bottle cap. You will see a dropper in the top of the bottle. It is ready to use. Hold the bottle upside down. A drop will form at the end of the dropper. Let the drop fall directly into your mouth. You can catch the drop on a spoon if this is easier.

If the drops do not come out of the bottle straight away, tap the bottle gently until a drop forms.

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How much One-Alpha to take

Your doctor will tell you how many drops to take, or to give to your child.

One-Alpha is only to be taken by mouth.

Be careful not to take more drops than you should. You must check with your doctor or pharmacist if you are not sure how to take this medicine correctly. This medicine is very strong (concentrated).

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, phosphate, 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 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 drops 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 that 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 children weighing more than 20 kilograms:

The usual starting dose is 10 drops each day. People usually take between 10 and 30 drops each day.

Most people take between 3 and 10 drops 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 30 to 50 drops each day. Your doctor may prescribe another medicine called a calcium supplement to take as well as One-Alpha. This will help to keep the right amount of calcium in your blood.

Elderly:

The usual starting dose is 5 drops each day.

Children:

The dose depends on the weight of the child (called bodyweight).

• Newborn and premature babies:

The usual starting dose is 1 to 2 drops per 2 kilograms of bodyweight each day.

If the level of calcium in their blood is very low, up to 40 drops per 2 kilograms of bodyweight may be needed each day.

A dose of 2 drops per 2 kilograms bodyweight each day is used to stop low blood calcium levels in premature babies.

• Children weighing less than 20 kilograms:

The usual starting dose is 1 drop per 2 kilograms bodyweight each day.

If you take more One-Alpha 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 One-Alpha

If you forget to take your medicine take it as soon as you remember. Then take the next dose at the usual time.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

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.

You should 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. These side effects may affect up to 1 in 10 people:

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

You should 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):

- Kidney problems:
 - 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 which may affect up to 1 in 10 people are:

- Abdominal/stomach pain or discomfort
- Rash
- Itch.

Uncommon possible side effects which may affect up to 1 in 100 people are:

- Headache
- Diarrhoea, vomiting, constipation, nausea
- Muscle pain
- Fatigue
- Calcinosis (deposits of calcium in the body)
- Feeling weak or unwell.

Rare possible side effects which may affect up to 1 in 1,000 people are:

- Dizziness.

Side effects with unknown frequency (cannot be estimated from the available data):

- Confusion
- Hives (urticaria).

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRC Pharmacovigilance, website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store One-Alpha®

- Keep this medicine out of the sight and reach of children.
- Do not take this medicine after the expiry date which is stated on the carton and bottle label (EXP). The expiry date refers to the last day of that month.
- Store in a refrigerator (2 to 8°C). After opening, you should discard the drops after 4 months. Write the date you first opened the bottle in the space provided on the carton.
- Store the bottle in the outer carton.

Do not throw away any medicines via waste water or household waste. 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 One-Alpha contains

- The active ingredient is alfacalcidol. One-Alpha contains 2 micrograms of alfacalcidol in each millilitre (ml). Each drop contains 0.1 microgram of alfacalcidol.
- The other ingredients are citric acid monohydrate (E330), ethanol, methylparahydroxybenzoate (E218), macroglycerol hydroxystearate, purified water, sodium citrate (E331), sorbitol (E420) and all-rac- α -tocopherol. You can find important information about some of the ingredients in your medicine near the end of section 2 of this leaflet.

What One-Alpha looks like and contents of the pack

One-Alpha is a solution of oral drops. One-Alpha is a slightly hazy or clear colourless solution.

One-Alpha comes in an amber glass bottle containing 10 or 20 ml. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
CHEPLAPHARM Arzneimittel GmbH, Ziegelhof 24,
17489 Greifswald, Germany

Manufacturer:
LEO Pharma A/S, DK-2750, Ballerup, Denmark.

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