PACKAGE LEAFLET: INFORMATION FOR THE USER

One-Alpha® 0.25 micrograms soft capsules
(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 0.25 micrograms soft capsules 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 bones due to lack of calcium (rickets or osteomalacia).
- Brittle bones (osteoporosis).

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 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 listed in the 'Other medicines and One-Alpha' section.
- If you have any problems with your kidneys. This includes if you have kidney stones.
- If you have granulomas or sarcoidosis. You may be more sensitive to One-Alpha.

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, patients with an overactive parathyroid gland or patients on regular haemodialysis. 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 is to maintain the right amount of phosphate in your blood.
- Your doctor may also prescribe a calcium supplement to take as well as One-Alpha. This is to maintain 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.
- 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.

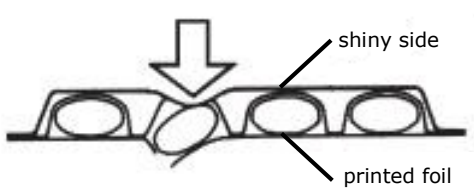
Important information about some of the ingredients in One-Alpha
One-Alpha contains:
- Sesame oil. This may rarely cause severe allergic reactions.

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 take the capsule out of the blister
Press on the shiny side of the blister so that the capsule comes out through the printed foil. Please see the diagram.



Each One-Alpha 0.25 microgram capsule contains 0.25 micrograms of alfacalcidol. These are cream coloured capsules.

How much One-Alpha to take
Your doctor will tell you how many capsules to take, or to give to your child.

Be careful not to take more capsules than you should.

You must check with your doctor or pharmacist if you are not sure how to take this medicine correctly.

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 getting 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 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 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. Your doctor will tell you what dose to take.

Adults
The usual starting dose for adults is 1 microgram per day.

People usually take between 0.5 and 6 micrograms per day until their blood tests show the medicine is working. After this, most people only need between 0.25 and 2 micrograms per day.

If you have very low levels of calcium in your blood, your doctor may prescribe between 3 and 5 micrograms per day. Your doctor may also prescribe another medicine, a calcium supplement to take as well as One-Alpha. This will help keep the right amount of calcium in your blood.

Elderly
The usual starting dose is 0.5 micrograms per day.

Children
The dose depends on the weight of the child (called bodyweight).
A liquid formulation is available for babies and small children who are unable to swallow capsules.

The starting dose for older children is usually as follows:

- **Children weighing more than 20 kilograms:**
  The usual starting dose is 1 microgram per 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 about taking this medicine, please 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 straight away 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 as soon as possible if you spot any of the following signs, which may be due to too much calcium or phosphate in your blood. This side effect may affect up to 1 in 10 people.
- **You need to pass water (urine) more often**
- **You feel thirsty**
- **You feel fatigue**
- **You feel sick, vomit, have constipation or diarrhoea or have lost your appetite**
- **You are sweating a lot**
- **You are having headaches**
- **You feel dizzy**

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:
- Confusion
- Headache
- Diarrhoea, vomiting, constipation, nausea
- Muscle pain
- Fatigue
- Calcinosis (deposits of calcium in the body)
- Kidney problems
  - Needing to pass water (urine) less often
  - Swelling of any part of your body
  - Fever with a pain in your side

These are signs that there may be problems developing with your kidneys. Kidney stones may be forming. Kidney stones may cause a sharp spasm or pain in one side of your lower back.

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

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
HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2
Tel: +353 1 6764971 Fax: +353 1 6762517
Website: www.hpra.ie E-mail: medsafety@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 store above 25°C.
- Do not use this medicine after the expiry date (Exp) which is marked on the carton and blister strips. This refers to the last day of that month.
- Do not use this medicine if you notice discoloration, damage or any other signs of deterioration.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away any 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 substance, which treats your illness is alfacalcidol.
  Each capsule contains 0.25 micrograms of alfacalcidol.
- The other ingredients are: sesame oil, all-rac-α-tocopherol, gelatin, glycerol (E422), potassium sorbate (E202) and titanium dioxide (E171).

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 are cream-coloured, egg shaped soft gelatin capsules holding 0.1g oily solution.
- The capsules are supplied in blister packs of 30.

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

Procured from within the EU and repackaged by:
Doncaster Pharmaceuticals Group Ltd, Kirk Sandall, Doncaster, DN3 1QR, UK.

PPA holder:
Imbat Ltd., Unit L2, North Ring Business Park, Santry, Dublin 9.

Distributed by:
Eurodrug Ltd., Unit L2, North Ring Business Park, Santry, Dublin 9.

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