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 soft capsules will be called One-Alpha.

What is One-Alpha®?

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

One-Alpha® is used to treat:
• 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).
• Changes in bone caused by kidney failure (osteodystrophy). 
• Bile acid sequestrants such as cholestyramine: for lowering your cholesterol level, or to help stop some types of diarrhoea or indigestion. You may get too much magnesium in your blood.
• 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.
• Cardiac glycosides, such as digoxin: for heart problems. You may get too much calcium in your blood. This may cause an abnormal heart beat.
• Antacids containing magnesium: for heartburn or indigestion. You may get too much magnesium in your blood.
• Calcium-containing medicines. You may get too much calcium in your blood.
• Acid-reducing medicines (e.g. omeprazole), used to treat heartburn and indigestion. You may get too much calcium in your blood.
• Other medicines that contain vitamin D. You may get too much calcium in your blood. 

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 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 "Taking other medicines" section below. 
• 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, 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.

You may get too much calcium or phosphate in your blood.

3. How to take One-Alpha®

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

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, 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 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 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 1 microgram each day. This is either 1 brown capsule, 2 red capsules or 4 white capsules.

People usually take between 1 and 3 micrograms each day.

Most people take between 0.25 and 1 microgram each day once the blood test results show the medicine is working. This is usually one white capsule, or one red capsule or one brown capsule.

If you have very low levels of calcium in your blood, your doctor may prescribe 3 micrograms 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 level in your blood.

You should tell your doctor right away 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
- Calcification (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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store One-Alpha™

- Keep out of the sight and reach of children.
- Do not take this medicine after the expiry date which is stated on the carton and blister blister (EDP). The expiry date refers to the last day of that month.
- Do not store above 25°C.
- 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 0.25 microgram soft capsules contain 0.25 microgram of alfacalcidol in each capsule.
- One-Alpha 0.5 microgram soft capsules contain 0.5 microgram of alfacalcidol in each capsule.
- One-Alpha 1 microgram soft capsules contain 1 microgram of alfacalcidol in each capsule.
- The other ingredients are sesame oil, all-rac-α-tocopherol, gelatin, glycerol, and potassium sorbate.
- The 0.25 microgram capsules also contain titanium dioxide (E171).
- The 0.5 microgram capsules also contain titanium dioxide (E171) and red iron oxide (E126).
- The 1 microgram capsules also contain black iron oxide (E172) and red iron oxide (E172).

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 0.25 microgram soft capsules are white capsules. One-Alpha 0.5 microgram soft capsules are red capsules. One-Alpha 1 microgram soft capsules are brown capsules. One-Alpha comes in blister packs of 30 capsules.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

LEO Laboratories Limited, Hurley, Berkshire SL6 6RJ, UK.

Manufacturer:

LEO Pharma A/S, DK 2750, Ballerup, Denmark.

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