

PACKAGE LEAFLET: INFORMATION FOR THE USER**One-Alpha® Drops**
(alfacalcidol)

Your medicine is available using the name One-Alpha Drops but will be referred to as One-Alpha throughout this leaflet.

Please read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects become serious, or you notice any side effects not listed in this leaflet please tell your doctor or pharmacist.

In this leaflet:

1. What One-Alpha is and what it is used for
2. Before you take One-Alpha
3. How to take One-Alpha
4. Possible side effects
5. How to store One-Alpha
6. Further information

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

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 changing. 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. 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 know that you have any sugar intolerance. You may have inherited this condition from someone else in your family.

If you are unsure if any of the above apply to you, talk to your doctor before taking One-Alpha.

Take special care with One-Alpha

Before you take One-Alpha tell your doctor:

- If you are taking another type of medicine called a cardiac glycoside, such as digoxin. These medicines are used to treat problems with your heart.
- If you have any problems with your kidneys. This includes if you have kidney stones.

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.

Taking other medicines

Please tell your doctor or pharmacist if you are taking, or have recently taken 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 epilepsy or fits. You may need a larger dose of One-Alpha.
- Barbiturates: for sleeping disorders. 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.
- Colestyramine: 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.
- 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.

Pregnancy and breast-feeding

Please ask your doctor or pharmacist for advice before taking One-Alpha:

- If you are pregnant, or think you are pregnant.
- If you are breast-feeding.

Tell your doctor if you become pregnant while 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 that may stop you from driving or using machines.

Important information about some of the ingredients of One-Alpha

One-Alpha contains:

- Ethanol. This is an alcohol. This medicine contains a very small amount of ethanol.
- Methylparahydroxybenzoate. This is a preservative. It may give you an allergic reaction. This may happen at any time after you take your medicine. Please read section 4 of this leaflet so you can spot any signs this may be happening to you.
- Polyoxyl 40 hydrogenated castor oil. This is used to make your medicine. It may give you an upset stomach or diarrhoea.
- Sorbitol. This is a type of sugar. If you cannot tolerate any sugar (sometimes called sugar intolerance) contact your doctor before you take this medicine. Your medicine contains 22.6 milligrams of sorbitol in one drop.

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

3. How to take One-Alpha

Always use One-Alpha exactly as your doctor has told you. You should 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.

How much One-Alpha to take

Your doctor will tell you how many drops to take, or to give 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, 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 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:

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, the 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.
- **Children weighing more than 20 kilograms:**
The usual starting dose is 10 drops 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 about taking this medicine, please ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, One-Alpha 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:

- **You need to pass water (urine) more often**
- **You feel thirsty**
- **You have a dry mouth, or a metallic taste in your mouth**
- **You feel weak or have pain in your muscles or bones**
- **You feel sick or have constipation.**

Other possible side effects:

Skin problems:

- Itching skin
- Rash
- Hives (urticaria)

Kidney problems:

- Needing to pass water (urine) less often.
- Swelling of any parts 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 in one side of your lower back.

The possible side effects described in this section of the leaflet probably affect about 1 in 10,000 people. Skin problems or too much calcium in your blood are the side effects most people get.

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 use the drops after the expiry date on the carton and bottle. The expiry date is the last day of that month.

Store in a refrigerator (2-8°C). After opening, you should discard the drops after 28 days. Write the date you first opened the bottle in the space provided on the carton.

Store the bottle in the outer carton.

If your doctor decides to stop your treatment, take any leftover medicine back to the pharmacy.

If your medicine appears to be discoloured or shows any other signs of deterioration, take them to your pharmacist who will advise you.

Medicines should not be disposed of via household wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What One-Alpha contains

The active ingredient is alfacalcidol. Each drop contains 0.1 microgram (100 nanograms) alfacalcidol. Also contains ethanol, polyoxyl 40 hydrogenated castor oil, methylparahydroxybenzoate, citric acid monohydrate, sodium citrate, sorbitol α -tocopherol and purified water.

What One-Alpha looks like and contents of the pack

One-Alpha is a solution of oral drops. One-Alpha is a clear, colourless solution. One-Alpha is available in amber glass bottles containing 10ml.

Manufacturer

One-Alpha is manufactured by: LEO Pharmaceutical Products, Ballerup, Denmark.

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

Product Licence holder: Landmark Pharma Ltd., 7 Regents Drive, Prudhoe, Northumberland, NE42 6PX.

PL No: 21828/0543

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PACKAGE LEAFLET: INFORMATION FOR THE USER

Alfacalcidol 2 micrograms/ml Oral Drops

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Please read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects become serious, or you notice any side effects not listed in this leaflet please tell your doctor or pharmacist.

In this leaflet:

1. What Alfacalcidol is and what it is used for
2. Before you take Alfacalcidol
3. How to take Alfacalcidol
4. Possible side effects
5. How to store Alfacalcidol
6. Further information

1. What Alfacalcidol is and what it is used for

Alfacalcidol 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.

Alfacalcidol 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.

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- 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. Before you take Alfacalcidol

Do not take Alfacalcidol

- 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 know that you have any sugar intolerance. You may have inherited this condition from someone else in your family.

If you are unsure if any of the above apply to you, talk to your doctor before taking Alfacalcidol.

Take special care with Alfacalcidol

Before you take Alfacalcidol tell your doctor:

- If you are taking another type of medicine called a cardiac glycoside, such as digoxin. These medicines are used to treat problems with your heart.
- If you have any problems with your kidneys. This includes if you have kidney stones.

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 Alfacalcidol 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 Alfacalcidol. This will help to keep the right amount of phosphate in your blood.

Taking other medicines

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Pregnancy and breast-feeding

Please ask your doctor or pharmacist for advice before taking Alfacalcidol:

- If you are pregnant, or think you are pregnant.
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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 that may stop you from driving or using machines.

Important information about some of the ingredients of Alfacalcidol

Alfacalcidol contains:

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- Sorbitol. This is a type of sugar. If you cannot tolerate any sugar (sometimes called sugar intolerance) contact your doctor before you take this medicine. Your medicine contains 22.6 milligrams of sorbitol in one drop.

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

3. How to take Alfacalcidol

Always use Alfacalcidol exactly as your doctor has told you. You should 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.

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How much Alfacalcidol to take

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You may also have other tests such as X-rays. This is also so your doctor knows that the dose is right for you.

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Adults:

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, the 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 Alfacalcidol. 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:**
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If you take more Alfacalcidol 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 Alfacalcidol

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, Alfacalcidol 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:

- **You need to pass water (urine) more often**
- **You feel thirsty**
- **You have a dry mouth, or a metallic taste in your mouth**
- **You feel weak or have pain in your muscles or bones**
- **You feel sick or have constipation.**

Other possible side effects:

Skin problems:

- Itching skin
- Rash
- Hives (urticaria)

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5. How to store Alfacalcidol

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Medicines should not be disposed of via household wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What Alfacalcidol contains

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What Alfacalcidol looks like and contents of the pack

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Manufacturer

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

Product Licence holder: Landmark Pharma Ltd., 7 Regents Drive, Prudhoe, Northumberland, NE42 6PX.

PL No: 21828/0543

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