

Package leaflet: Information for the user

One-Alpha[®] Injection

alfacalcidol

Read all of this leaflet carefully before you start having 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 Injection 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 have One-Alpha[®]
3. How to use 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 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. What you need to know before you have One-Alpha[®]

Do not have 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 having One-Alpha.

Warnings and precautions

Talk to your doctor or nurse before having 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 alfacalcidol.

This medicine contains small amounts of alcohol. This may be harmful to some patients such as patients with liver disease, epilepsy and those suffering from alcoholism.

You may get too much calcium or phosphate in your blood when you have 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 having 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 have 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 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.
- 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.

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 having 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 of One-Alpha

One-Alpha contains:

- Ethanol. This is an alcohol. This medicinal product contains up to 160 mg ethanol per dose (corresponding to 4 micrograms of alfacalcidol), which is equivalent to 10 vol % . The amount of ethanol in each dose of One-Alpha is equivalent to less than 4 ml beer or 1.7 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.
- Sodium. This medicine contains less than 1 mmol sodium per dose (corresponding to 4 micrograms of alfacalcidol), that is to say essentially 'sodium free'.
- Propylene glycol. One-Alpha solution for injection contains 415 mg propylene glycol per ml which is equivalent to 20.75 mg/kg/day (corresponding to 0.1 micrograms/kg/day of alfacalcidol). If your baby is less than 4 weeks old, talk to your doctor or pharmacist before giving them this medicine, in particular if the baby is given other medicines that contain propylene glycol or alcohol.

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

3. How to use One-Alpha®

One-Alpha will be given to you by a doctor or nurse.

How much One-Alpha to have

Your doctor or nurse will give you One-Alpha because it is an injection

This injection goes into your vein. This may be called IV (intravenous) by your doctor or nurse.

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 having 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 have more or less medicine depending on your test results.

You may get too much calcium or phosphate in your blood when you have 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 have 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 have half the dose you had before.

Adults and children weighing more than 20 kilograms:

The usual starting dose is 1 microgram each day. People usually have between 1 and 3 micrograms each day.

Most people have between 0.25 and 1 microgram 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 3 and 5 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 in your blood.

Elderly:

The usual starting dose is 0.5 microgram each day.

Children:

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

Newborn and premature babies:

The usual starting dose is 0.05 to 0.1 microgram per kilogram of bodyweight each day.

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

A dose of 0.1 microgram per kilogram 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 0.05 microgram per kilogram bodyweight each day.

If you have more One-Alpha than you should

Your doctor or nurse will give you this medicine. If you think you may have been given too much, tell your doctor or nurse straight away. You may need to stop having 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 have One-Alpha

Your doctor or nurse will give you this medicine. If you think that you have missed a dose then tell your doctor or nurse.

If you have any further questions on the use of this medicine, please 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 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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. 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 this medicine after the expiry date which is stated on the ampoule. The expiry date refers to the last day of that month.
- Store at 2 to 8°C (in a refrigerator).
- Keep the ampoule in the outer carton in order to protect it from light.

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).
- The other ingredients are citric acid, ethanol, propylene glycol, sodium citrate and water for injection.

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 clear colourless solution for injection.

One-Alpha comes in one-point-cut amber glass ampoules containing 0.5 or 1 ml.

There are 10 ampoules in a carton.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder: Neon Healthcare Limited, 8 The Chase, John Tate Road, Hertford, SG13 7NN, United Kingdom

Manufacturer: CENEXI SAS, 52 rue Marcel et Jacques Gaucher, 94120 Fontenay-sous-Bois, France.

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