

One-Alpha[®]

Alfacalcidol (*al-far-cal-see-dol*)

Capsules: 1 µg or 0.25 µg alfacalcidol

Drops: 2 µg/mL alfacalcidol

Consumer Medicine Information (CMI)

Please read this leaflet carefully before you start your treatment.

Keep this leaflet. You may want to read it again.

What is in this leaflet?

This leaflet answers some common questions about One-Alpha[®]. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking One-Alpha[®] against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

What One-Alpha[®] is used for?

One-Alpha[®] capsules and drops both contain a type of vitamin D called alfacalcidol (*al-far-cal-see-dol*). Vitamin D controls the levels of two substances called calcium and phosphate in your body. Your body needs both calcium and phosphate 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 disease.
- High or low levels of calcium in the blood due to changes in small hormone glands found in the neck. If the amount of hormone produced by these glands is increased or decreased, it can affect calcium levels in the blood.
- Low levels of calcium in the blood of newborn babies.
- Softening and/or a change in shape of the bones due to lack of calcium.

Your doctor may have prescribed One-Alpha[®] for another reason. Ask your doctor or pharmacist if you have any questions about why One-Alpha[®] has been prescribed for you.

Before you use One-Alpha[®]

When you must not use One-Alpha[®]

If you are allergic (hypersensitive) to alfacalcidol or any of the other ingredients listed at the end of this leaflet.

If you know you have high levels of calcium in your blood (called hypercalcaemia).

If you know you have high levels of calcium in your body tissue (called calcification).

Do not use One-Alpha[®] drops if you have any sugar intolerance.

You may have inherited this condition from someone else in your family.

If you are unsure if you have any of the conditions listed above, talk to your doctor before taking One-Alpha[®].

Do not use One-Alpha[®] after the expiry date (EXP) printed on the pack.

If you take this medicine after the expiry date has passed, it may not be as effective.

Do not use One-Alpha[®] if the packaging is torn, doesn't look quite right or shows signs of tampering.

If any of these apply, return the medicine to your pharmacist for disposal.

Do not use One-Alpha[®] to treat any other complaints without your doctor's permission.

Do not give One-Alpha[®] to anyone else even if they have the same condition as you.

Before you start to use One-Alpha[®]

Tell your doctor or pharmacist if:

- You are using any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food store.
- You are being treated with medicine for a heart condition. These medicines may be affected by One-Alpha[®] or may affect how well it works.

- You have problems with your kidneys. This includes if you have kidney stones.
- You have an allergy to sesame oil.
- You suffer from alcoholism, liver disease, or epilepsy.
- You are pregnant, or think you are pregnant.
- You are breast-feeding or planning to breast-feed. One-Alpha® is generally not recommended for use during breast-feeding.

What else you should know:

Your doctor may prescribe another medicine called a phosphate binding agent for you to take as well as One-Alpha®. This will help your blood maintain the right amount of phosphate.

The level of calcium or phosphate in your blood may become too high when you take this medicine. Please read the 'Side effects' section in this leaflet so you can recognise any signs this may be happening to you. Your doctor may need to change your dose.

Your doctor and pharmacist have more information on medicines you should be careful with or avoid whilst using One-Alpha®.

How to use One-Alpha®

Always use One-Alpha® exactly how your doctor has told you. You should check with your doctor or pharmacist if there is anything you are not sure about.

Your doctor may want to take weekly blood tests when you first start taking One-Alpha®. This is so the doctor knows that you are receiving the dose that is right for you. Your doctor may need to adjust your dose after the blood tests. When you are getting the correct dose you will not need blood tests as often.

Your doctor may also want you to have other tests such as X-rays.

This is also so your doctor can check that the dose of One-Alpha® you are taking is right for you.

How to take it:

Capsules

Press on the plastic side of the blister. The capsule will come out through the printed side of the foil. Swallow the capsule. The capsule can be taken with food or water, although this is not necessary.

Adults:

For adults, the usual starting dose is 1 microgram per day (this is, 1 brown capsule or 4 white capsules). People usually take between 1 and 3 micrograms each day.

Once the blood test results show the medicine is working, most people take between 0.25 and 1 microgram per day (this is usually 1 brown capsule or 1 white capsule).

Your doctor will tell you how much to take.

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

Elderly:

For elderly patients, the usual starting dose is 0.5 micrograms per day (this is usually 2 white capsules).

Your doctor will tell you how much to take.

Children:

In children, the dose depends on the weight of the child (called bodyweight). Your doctor will tell you how much to take.

Drops

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.

Adults:

For adults, the usual starting dose is 10 drops per day.

Once the blood test results show the medicine is working, most people take between 3 and 10 drops per day.

Your doctor will tell you how much to take.

If you have very low levels of calcium in your blood, your doctor may prescribe between 30 and 50 drops each day. Your doctor may prescribe another medicine called a calcium supplement to take as well as One-Alpha®. This will help keep the right amount of calcium in your blood.

Elderly:

For elderly patients, the usual starting dose is 5 drops per day. Your doctor will tell you how much to take.

Children:

In children, the dose depends on the weight of the child (called bodyweight). Your doctor will tell you how much to take.

How long to use it

Your doctor will tell you how long to use One-Alpha®.

Ask your doctor or pharmacist if you have any questions about how long you should use One-Alpha®.

If you forget to take it

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

Ask your doctor or pharmacist if you have any further questions about taking One-Alpha®.

If you use too much or use it other than directed (Overdose)

If you are not sure what to do, ask your doctor or pharmacist.

If you use too much or use it other than directed (Overdose) immediately telephone your doctor or the Poisons Information Centre (Telephone 0800 764 766 in New Zealand) for advice, or go to the Emergency Department at the nearest hospital, if you think that you or anyone else may have used too much of One-Alpha®. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using One-Alpha®

Things to be careful of

Be careful driving or operating machinery until you know how One-Alpha® affects you.

One-Alpha® has no or negligible direct influence on the ability to drive and use machines.

Check with your doctor if you feel any side effect, such as dizziness that may stop you from driving or using machines.

Things you must do

Tell your doctor or pharmacist if you are intending to or become pregnant while using One-Alpha®.

If you are about to be started on any new medicine, tell your doctor or pharmacist that you are using One-Alpha®.

Tell your doctor if for any reason you have not used One-Alpha® as directed.

Otherwise your doctor may think that it was not effective and change your treatment unnecessarily.

Things you must not do

Do not give One-Alpha® to anyone else, even if they have the same condition as you.

Side effects

Tell your doctor or pharmacist if you do not feel well while you are using One-Alpha®.

Like other medicines One-Alpha® can cause some side effects. If they occur, most are likely to be minor and temporary. However, some may be serious and require medical attention.

Ask your doctor or pharmacist to answer any questions you may have.

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 notice 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

Tell your doctor or pharmacist if you notice any of the following side effects and they worry you:

- Itching skin
- Skin rash or hives
- Needing to pass water (urine) less often
- Swelling of any parts of your body
- Fever with a pain in your side

Some people may get other side effects while using One-Alpha®. Tell your doctor if you notice any unwanted side effect, especially if severe or persistent, or if there is a change in your health that you think might be caused by One-Alpha®.

Do not be alarmed by this list of side effects. You may not experience any of them.

These can be serious side effects. You may need urgent medical attention.

This is not a complete list of all side effects.

Tell your doctor or pharmacist if you have any additional unpleasant effects while you are using One-Alpha®.

After using One-Alpha®

Storage

Keep out of the reach and sight of children.

Do not use after the expiry date stated on the package.

Capsules - One-Alpha® capsules must be stored in a cool dry place where the temperature stays below 25°C.

Drops - One-Alpha® drops must be stored in a refrigerator (2- 8°C). Do not freeze. The bottle should be stored in the outer carton.

Capsules and drops should be protected from light.

Disposal

Disposal

If your doctor or pharmacist tells you to stop using One-Alpha® or it has passed its expiry date, ask your doctor or pharmacist what to do with any leftover medicine. Medicines should not be thrown away in waste water or in household waste as this may cause damage to the environment.

If you have any further questions about One-Alpha® capsules or drops please consult your doctor or pharmacist.

Product description

What One-Alpha® looks like

One-Alpha® capsules are smooth white (0.25 microgram) or brown (1 microgram) oval capsules that are 8 mm in length. These are stored in a blister pack of 30 capsules that are within an outer carton.

One-Alpha® drops comprise a glass bottle containing a clear, colourless solution. The bottle is stored within in an outer carton.

Ingredients

One-Alpha® capsules contain alfacalcidol (active agent), sesame oil, α-tocopherol, gelatine, and glycerol and potassium sorbate.

The 0.25 microgram capsules also contain titanium dioxide (E171).

The 1 microgram capsules also contain black iron oxide (E172) and red iron oxide (E172).

One-Alpha® drops contain alfacalcidol (active agent), citric acid monohydrate, ethanol, methylparahydroxybenzoate, polyoxyl 40 hydrogenated castor oil (macroglycerol hydroxystearate), purified water, sodium citrate, sorbitol, methyl parahydroxybenzoate and α-tocopherol.

This is not all the information available on One-Alpha®. If you have any more questions or are unsure about anything, ask your doctor or pharmacist.

Distributor

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This leaflet was prepared in September 2021.

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