

ALFACIP CAPSULES

Alfacalcidol (0.25mcg, 1mcg)

Consumer Medication Information Leaflet (RiMUP)

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What Alfacid capsules 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.

- 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).

How Alfacid capsules works

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.

Alfacalcidol 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).

Before you use Alfacid capsules

When you must not take it

- If you are allergic (hypersensitive) to alfacalcidol or any of the other ingredients.
- 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 taking alfacalcidol

Before you start to take it

- 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 6 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

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 alfacalcidol.
- *Barbiturates*: for sleeping disorders. You may need a larger dose of alfacalcidol.
- *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 alfacalcidol 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.

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How to use Alfacip capsules

How much to take

Always use alfacalcidol exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

When to take it

Your doctor will tell you how many capsules to take, or 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.

How long to take it

The usual starting dose is 1 microgram each day. This is 1 red capsule or 4 Green 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 green capsule, or one red capsule.

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 alfacalcidol. This will help to keep the right amount of calcium level in your blood.

Elderly:

The usual starting dose is 0.5 microgram each day. This is either 2 green capsules.

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.

Children weighing more than 20 kilograms

The usual starting dose is 1 microgram each day.

If you forget to take it

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.

If you take too much (overdose)

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.

While you are using it

Things you must do

You must tell your doctor/ pharmacist about any herbal/ OTC drugs/ special diet you are currently taking/ or undergoing any medication for other conditions

You must keep away all the medicines away from children

Things you must not do

You must not exceed the recommended dosage

Things to be careful of

Please tell your doctor if you are pregnant/ planning to get pregnant/ or breastfeeding

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 may report any side effects or adverse drug reactions directly to National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-7883 5549 or visiting the website npra.gov.my [Consumers -> Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

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Storage and Disposal of Alfapip capsules

Storage

Store below 30° C.

Disposal

Medicines should not be thrown away in waste water or in household waste. Please ask your pharmacist how to throw away any medicine you do not need anymore. If you do this you will help protect the environment.

Product description

What it looks like?

Description of Alfapip 0.25 mcg:

Green transparent round shaped soft gelatin capsules

Description of Alfapip 1 mcg:

Red transparent round shaped soft gelatin capsule

Pack size

Carton containing 10 blister of 10 capsules each

Ingredients

The inactive Ingredients for Alfapip 0.25 mcg are as follows:

Alfa tochoferyl acetate, Ethanol, Corn oil, Gelatin, glycerol, Liquid Sorbitol, Methyl hydroxybenzoate, Propyl Hydroxybenzoate, Colour Brilliant Blue FCF supra, Colour Quinoline yellow water soluble and purified water.

The inactive Ingredients for Alfapip 1 mcg are as follows:

Alfa tochoferyl acetate, Ethanol, Corn oil, Gelatin, glycerol, Liquid Sorbitol, Methyl hydroxybenzoate, Propyl Hydroxybenzoate, Poneau 4R BIS 16255 and purified water.

MAL Number

Alfaip 0.25 mcg Capsules:

MA07091042X

Alfapip 1 mcg Capsules:

MAL07061574X

Manufacturer

Cipla Ltd, D7 ,MIDC, Area

Kurkumbh Dist.Pune 413802 INDIA.

Product Registration Holder

CIPLA MALAYSIA SDN BHD

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