Vitalpha-D

(Alfacalcidol)

0.5 mcg Tablets

وائٹ ایلفا۔ڈی

(ایلفا کالسیڈول)

۰٫۵ مائیکروگرام گولیاں

COMPOSITION:
Each tablet contains:
Alfacalcidol ..... 0.5 mcg.

INDICATIONS:
It is indicated in all conditions where there is a disturbance of calcium metabolism due to impaired 1-α hydroxylation such as when there is reduced renal function. The main indications are:

- Renal osteodystrophy.
- Hyperparathyroidism (with bone disease).
- Hypoparathyroidism.
- Neonatal hypocalcaemia.
- Nutritional and malabsorptive rickets and osteomalacia.
- Pseudo-deficiency (D-dependent) rickets and osteomalacia.
- Hypophosphataemic vitamin D resistant rickets and osteomalacia.

Posology:
Initial dose for all indications:

- **Adults and children over 20 kg bodyweight:** 1 microgram/day.
- **Elderly:** 0.5 microgram/day.
- **Neonates and premature infants:** 0.05 - 0.1 microgram/kg/day.
- **Children under 20 kg bodyweight:** 0.05 microgram/kg/day.

The dose of should be adjusted thereafter to avoid hypercalcaemia according to the biochemical response. Indices of response include plasma levels of calcium (ideally corrected for protein binding), alkaline phosphatase, parathyroid hormone, as well as radiographic and histological investigations.

CLINICAL PHARMACOLOGY:
Pharmacodynamics:
Alfacalcidol is converted rapidly in the liver to 1,25-dihydroxyvitamin D. This is the metabolite of vitamin D which acts as a regulator of calcium and phosphate metabolism.

In patients with nutritional osteomalacia, increases in calcium absorption were noted within 6 hours of giving 1 µg 1α-OHD3 orally and usually peaked at 24 hours. 1α-OHD3 also produced increases in plasma inorganic phosphorus due to increased intestinal absorption and renal tubular re-absorption. This latter effect is a result of PTH suppression by 1α-OHD3. The effect of the drug on calcium was about double its effect on phosphorus absorption.

Patients with chronic renal failure have shown increased serum calcium levels within 5 days of receiving 1α-OHD3 in a dose of 0.5 - 1.0 µg/day. As serum calcium rose, PTH levels and alkaline phosphatase decreased toward normal.

Method of administration:
Oral.

ہدایات:

- **خوراک** ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
- دوا کو ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر روشنی سے بچا کر خشک جگہ پر رکھیں۔
- صرف رجسٹرڈ ڈاکٹر کے نسخے پر ہی فروخت کریں۔
- بچّوں کی پہنچ سے دور رکھیں۔

Manufactured by:
Kaizen Pharmaceuticals (Pvt.) Ltd.
E-127-129, North Western Industrial Zone,
Bin Qasim, Karachi-75020, Pakistan.

ART No.: 378/1

Before using this medicine, be sure to tell your doctor and pharmacist:
Do not take Vitalpha-D and tell your doctor:

• 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 Vitalpha-D.

WARNINGS AND PRECAUTIONS:
Talk to your doctor, pharmacist or nurse before taking.
• If you are taking any of the medicines in the "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 Vitalpha-D.

You may get too much calcium or phosphate in your blood when you take this medicine. Your doctor may need to change your dose. While you are taking 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 Vitalpha-D. 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 Vitalpha-D. This is to maintain the right amount of calcium in your blood.

Other medicines and Vitalpha-D:
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 Vitalpha-D.
• 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.
• Bile acid sequestrants such as cholestyramine: for lowering your cholesterol level, or to help stop some types of diarrhoea or itching. Your may not enter your blood as usual.

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 taking this medicine.

CONTRAINDICATIONS:
Hypersensitivity to the active substance or to any of the excipients.
Hypercalcaemia, metastatic calcification, hyperphosphatemia, or evidence of vitamin D overdose.

Other Possible Side Effects:
Like all medicines, this medicine can cause side effects, although not everybody gets them.
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. These side effects may affect up to 1 in 10 people.
Important side effects to look out for:
• 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.

STORAGE CONDITIONS AND INSTRUCTIONS
• Store below 30°C in a dry place, protect from light.
• To be dispensed on the prescription of a registered medical practitioner only.
• Keep out of the reach of children.

Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

PRESENTATION
Vitalpha-D 0.5mcg is available in blister pack of 10's.