Leaflet size as per **(Windol Tablet 0.5 mcg)** WnsFeild Pharmaceuticals

Front

KαID™
(Alfacalcidol)

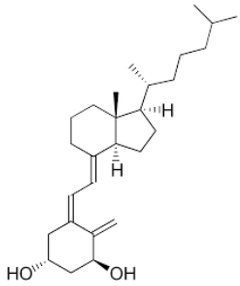
0.5 mcg
Tablet

کیڈ

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

Product Specs.: In-house

DESCRIPTION:
Alfacalcidol, or 1-alpha-hydroxycholecalciferol or 1-alpha-hydroxyvitamin D_3, is a non-endogenous analogue of vitamin D. It plays an essential function in calcium homeostasis and bone metabolism. Alfacalcidol is activated by the enzyme 25-hydroxylase in the liver to mediate its effects in the body, or most importantly, the kidneys and bones. The pharmacological actions of Alfacalcidol are prolonged than vitamin D because a negative feedback mechanism regulates the final activation step of vitamin D in the kidneys.
Alfacalcidol manages hypocalcemia, secondary hyperparathyroidism, and osteodystrophy in adults with chronic renal failure. In approving European countries, Alfacalcidol is also indicated for managing nutritional and malabsorptive rickets and osteomalacia, vitamin D-dependent rickets and osteomalacia, and hypophosphataemic vitamin D resistant rickets and osteomalacia.
Having the chemical formula $C_{27}H_{44}O_2$, below is the molecular structure for alfacalcidol.



CLINICAL PHARMACOLOGY:
Mechanism of Action: In conditions like chronic renal failure, renal bone disease, hypoparathyroidism, and vitamin D dependent rickets, the kidneys' capacity for 1α-hydroxylation is impaired, leading to reduced production of endogenous 1,25-dihydroxyvitamin D and aberrated mineral metabolism. As an active and potent analog of vitamin D, Alfacalcidol works to restore the functions and activities of endogenous 1,25-dihydroxyvitamin D.
Pharmacodynamics & Pharmacokinetics:
Alfacalcidol is absorbed passively and almost completely in the small intestine. Alfacalcidol works to increase serum levels of calcium by stimulating intestinal calcium absorption, reabsorption of calcium from bone, and possibly the renal reabsorption of calcium. It also modestly promotes intestinal phosphorus absorption. In patients with renal failure, Alfacalcidol increased intestinal calcium and phosphorus absorption in a dose-related manner. This increase in calcium and phosphorus levels occurs within three days following drug administration: this effect was reversed within three days of drug discontinuation. In patients with chronic renal failure, serum calcium levels were elevated while parathyroid hormone and alkaline phosphatase levels returned to normal levels within five days following Alfacalcidol administration. Since Alfacalcidol suppresses parathyroid hormone, a reduction in parathyroid hormone levels is achieved more rapidly in patients on intermittent intravenous therapy, with significant reductions occurring within three months of therapy. In patients receiving daily oral therapy of Alfacalcidol, the time it takes Alfacalcidol to normalize plasma calcium levels may be up to several months, possibly reflecting calcium being utilized for bone mineralization. In patients with nutritional osteomalacia, Alfacalcidol increased calcium absorption with six hours of oral administration and the effects peaked at 24 hours. The active metabolite of Alfacalcidol, 1,25-dihydroxyvitamin D, is transported to tissues via globulin, a specific transport protein. The half-life of Alfacalcidol ranges from three to four hours.

INDICATIONS:
Alfacalcidol is indicated in diseases caused by disturbances in the calcium metabolism due to abnormal vitamin D_3 metabolism. Adult patients with chronic renal failure for the management of hypocalcemia, secondary hyperparathyroidism, or osteodystrophy. Alfacalcidol is indicated in the management of nutritional and malabsorptive rickets and osteomalacia, vitamin D-dependent rickets and osteomalacia, and hypophosphataemic vitamin D resistant rickets and osteomalacia.

DOSAGE AND ADMINISTRATION:
Alfacalcidol should be administered once a day with or without food and/or drink. It is important to adjust the dosage according to the biochemical responses to avoid hypercalcemia. The daily dose can be individualized and titrated based on the state of renal function, degree of bone mineralization and initial plasma calcium and alkaline phosphatase concentrations.
Dosage for Adults:

Indication	Dose	General Maintenance Dose
Chronic Renal Failure	0.5 – 1.0 mcg	0.25 – 2 mcg Daily
Osteoporosis	0.5 – 1.0 mcg	
Hypoparathyroidism	1.0 - 4.0 mcg	
Disease associated with Vit. D Metabolism	1.0 - 4.0 mcg	

The requirements generally decrease in patients with: bone disease when there is biochemical or radiographic evidence of bone healing and in hypoparathyroidism patients after normal serum calcium level have been achieved.

PRECAUTIONS:
1. Should not be used concomitantly with other vitamin D products or derivatives
2. Alfacalcidol is a potent cholecalciferol derivative with a profound positive effect on intestinal absorption of dietary calcium, which may lead to hypercalcemia. Patients with renal bone disease and a relatively high initial plasma calcium and "autonomous" hyperparathyroidism are liable to onearly hypercalcemia, as are the minority of dialysis patients with low plasma alkaline phosphatase.
3. Hypercalcemia may be anticipated; hence patients should be informed about the clinical symptoms connected with hypercalcemia. Signs of hypercalcemia are anorexia, fatigue, nausea and vomiting, constipation or diarrhoea, polyuria, sweating, headache, polydipsia, hypertension, somnolence and vertigo.

Back

4. Prolonged hypercalcemia may aggravate arteriosclerosis or cardiac valve sclerosis and therefore prolonged hypercalcemia should be avoided when used in these patients. Alfacalcidol should also be used with caution in patients with calcification of pulmonary tissue as this may result in cardiac disease.
5. Alfacalcidol should be used with extreme caution in patients on digitalis glycosides – hypercalcemia may precipitate cardiac arrhythmias.
6. Prolonged hypercalcemia may aggravate nephrolithiasis and therefore prolonged hypercalcemia should be avoided when Alfacalcidol is used in these patients. Transient or even long-lasting deterioration of kidney function has been observed. In patients with renal bone disease or severely reduced renal function, a phosphate binding agent could be used simultaneously with Alfacalcidol to prevent increased serum phosphate and potential metastatic calcification.
7. Alfacalcidol should be used with caution in patients with granulomatous diseases such as sarcoidosis where the sensitivity to vitamin D is increased due to increased hydroxylation activity.

SPECIAL POPULATIONS:
Pregnancy: Do not use in pregnancy unless clearly necessary.
Breast feeding: Alfacalcidol maybe excreted in breast milk, therefore breast feeding should be avoided during treatment.
Paediatrics: Safety and efficacy data for children is not established. A rise in plasma creatinine (or a fall in glomerular filtration rate) has been reported in children with renal failure who are treated with Alfacalcidol. However, it is unclear whether this response was due to the action of the drug or to increased creatinine production during growth.

CONTRAINDICATIONS:
Alfacalcidol is contraindicated:
- In patients who are hypersensitive to this drug or to any ingredient in the formulation, including any non-medicinal ingredient, or component of the container.
- When there is biochemical evidence of hypercalcemia, hyperphosphatemia, or evidence of vitamin D overdose.

DRUG INTERACTIONS:
Alfacalcidol can have potential drug drug interaction with the following pharmacological agents, hence concomitant use should be evaluated carefully:
- Digitalis glycosides
- Mineral oils used as laxatives
- Thiazide diuretics
- Vitamin D
- Anticonvulsants (phenytoin, barbiturates, carbamazepine or primidone)
- Antacids containing magnesium
- Aluminium containing preparations (aluminium hydroxide, sucralfate)
- Bile acid sequestrants (cholestyramine)

ADVERSE REACTIONS:
Adverse effects are uncommon with Alfacalcidol. The adverse effects are similar to those encountered with excessive vitamin D intake.
Metabolism and nutrition disorders: Elevated blood urea nitrogen (BUN), albuminuria, hypercholesterolemia, elevated aspartate aminotransferase (AST or SGOT) and alanine aminotransferase (ALT or SGPT), anorexia, weight loss, polydipsia, hyperthermia, dry mouth, metallic taste.
Cardiac disorders: Cardiac arrhythmia, hypertension
Eye disorders: Conjunctivitis, corneal calcification, photophobia
Infections and Infestations: Rhinorrhea
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Renal and urinary disorders: Polyuria, nocturia
Reproductive system and breast disorders: Decreased libido
General disorders and administration site conditions Fatigue, weakness.

OVERDOSAGE:
Over dosage of Alfacalcidol can lead to hypercalcemia, hypercalciuria and hyperphosphatemia. Treatment of hypercalcemia due to overdosage or accidental overdosage includes discontinuations of treatment with Alfacalcidol, general supportive measures, IV hydration for forced diuresis, monitor electrolytes, monitor renal function indices and monitor ECG abnormalities. Gastric lavage or induction of emesis may help in acute overdosage; administration of mineral oils may promote fecal elimination.

INSTRUCTIONS:
- Store below 30°C.
- Protect from heat, sunlight & moisture.
- Keep out of the reach of children.
- To be sold on the prescription of a registered medical practitioner only.

PRESENTATION:
KAID tablet 0.5 mcg : Pack of 2 x 10 tablets.

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گرمی، دھوپ اور نمی سے بچائیں۔
بچوں کی پہنچ سے دور رکھیں۔
صرف مستند ڈاکٹر کے نسخہ پر فروخت کریں۔

Manufactured by:
WnsFeild Pharmaceuticals.
Plot # 122, Block A, Phase V, Industrial Estate, Hattar, Pakistan.

FOR FURTHER INFORMATION PLEASE CONTACT:

CCL
Marketed by:
CCL Pharmaceuticals (Pvt.) Ltd.
62 Industrial Estate, Kot Lakhpat, Lahore, Pakistan.

zoom view

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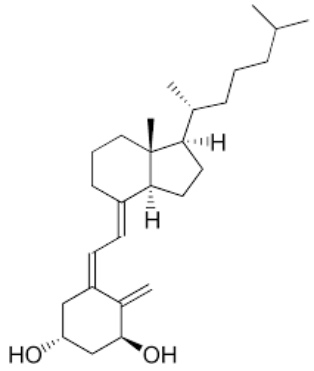

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