

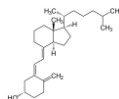

PACKAGE INSERT
Cholecalciferol (Vitamin D3) Injection IP
CALOZIM™-600K

COMPOSITION:

Each ml contains
 Cholecalciferol IP 6,000,000IU
 (Vitamin D3)
 Oil Base q.s.

PROPERTIES:

In its biologically active form vitamin D3 stimulates intestinal calcium absorption, incorporation of calcium into the osteoid, and release of calcium from bone tissue. Its empirical formula is $C_{27}H_{44}O$ and molecular weight is 384.64 g/mol. Structural formula is as shown:

**CLINICAL PHARMACOLOGY:****PHARMACODYNAMICS**

Pharmacotherapeutic group: Vitamin supplements, ATC code: A11C.C05

In its biologically active form vitamin D₃ stimulates intestinal calcium absorption, incorporation of calcium into the osteoid, and release of calcium from bone tissue. In the small intestine it promotes rapid and delayed calcium uptake. The passive and active transport of phosphate is also stimulated. In the kidney, it inhibits the excretion of calcium and phosphate by promoting tubular resorption. The production of parathyroid hormone (PTH) in the parathyroids is inhibited directly by the biologically active form of vitamin D₃. PTH secretion is inhibited additionally by the increased calcium uptake in the small intestine under the influence of biologically active vitamin D₃.

PHARMACOKINETICS

The pharmacokinetics of vitamin D₃ is well known.

Absorption:

Vitamin D₃ is well absorbed from the gastro-intestinal tract in the presence of bile.

Distribution and Biotransformation:

Vitamin D₃ is hydroxylated in the liver to form 25-hydroxycholecalciferol and then undergoes further hydroxylation in the kidney to form the active metabolite 1, 25 dihydroxycholecalciferol (calcitriol). The metabolites circulate in the blood bound to a specific α -globulin.

Elimination:

Vitamin D₃ and its metabolites are excreted mainly in the bile and faeces.

INDICATIONS:

Cholecalciferol is indicated for treatment and prevention of vitamin D₃ deficiency in adults, elderly and children over 12 years of age.

DOSE AND ADMINISTRATION:

The dosage is determined by the desired Vitamin D₃ levels. Colecalciferol Injection IP 600000 IU/ml can be given once or as directed by the physician by intramuscular injection.

Method of administration: Intramuscular

CONTRAINDICATIONS:

Known hypersensitivity to Vitamin D₃, hypercalcemia, abnormal sensitivity to the toxic effects of vitamin D₃, hypervitaminosis D.

WARNING AND PRECAUTIONS:

Excessive intake may lead to development of hyperphosphataemia or hypercalcaemia. Infants, renal impairment or calculi, heart disease. Monitor plasma phosphate and calcium level.

DRUG INTERACTIONS:

Mineral Oil, Cholestyramine, Colestipol: Intestinal absorption of Vitamin D₃ may be impaired when co-administered.

Thiazides Diuretics: Concurrent administration of thiazide diuretics and Vitamin D₃ to hypoparathyroid patients may cause hypercalcemia which may be transient or may require discontinuation of vitamin D₃.

Antiepileptic (e.g. carbamazepine, phenobarbitone, phenytoin and primidone): may increase Vitamin D₃ requirements.

Rifampicin and Isoniazid: May reduce efficacy of Vitamin D₃. Corticosteroids : May counteract the effect of Vitamin D₃.

PREGNANCY AND LACTATION:**Pregnancy**

The use of Vitamin D₃ in excess of the recommended dietary allowance during normal pregnancy should be avoided unless, in the judgment of the physician, potential benefits in a specific case outweigh the significant hazardous involved.

Lactation

Vitamin D₃ is distributed into breast milk and concentration appears to correlate with the amount of Vitamin D₃ in the serum of exclusively breast-fed infants hence its use should be weighted against the risks involved.

SIDE EFFECTS:

Vitamin D₃ analogs are well tolerated in normal daily doses. Chronic excessive dosing can lead to toxicity and hypervitaminosis D.

OVERDOSE:*Symptoms:*

Acute intoxication with vitamin D₃ analogues may cause hypervitaminosis D (See Warning and precautions).

Treatment:

Treatment of acute chronic intoxication includes withdrawal of the vitamin D₃ analogues and any calcium supplements, administration of oral or IV fluids and possibly corticosteroids or calciuric diuretics such as furosemide and ethacrynic acid. Peritoneal or hemodialysis with calcium free dialysate will help remove calcium.

If acute ingestion is recent, gastric lavage or emesis may minimize further absorption. If the drug has already passed through the stomach, administration of mineral oil may promote faecal elimination.

Hypocalcaemia is usually reversible; however if metastatic calcification has occurred, severe renal or cardiac failure or even death may result.

STORAGE CONDITIONS:

Store in a cool, dry & dark place. Protected from direct sunlight.

SHELF LIFE:

24 Months

DOSEAGE FORM AND PACKAGING AVAILABLE:

Cholecalciferol (Vitamin D3) Injection IP 600000IU is packed in the 1ml clear colourless glass ampoule

DATE OF REVISION:

May 2024

MANUFACTURED BY:

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