

Composition:

3D™ 2000 IU Tablet: Each film coated tablet contains Vitamin D₃ 2000 IU as Cholecalciferol USP.

3D™ 20000 IU Capsule: Each capsule contains Vitamin D₃ 20000 IU as Cholecalciferol USP.

3D™ 40000 IU Capsule: Each capsule contains Vitamin D₃ 40000 IU as Cholecalciferol USP.

Pharmacology:

Vitamin D metabolites promote the active absorption of calcium and phosphorus by the small intestine, thus elevating serum calcium and phosphate levels sufficiently to permit bone mineralization.

It is also necessary for utilization of both Calcium and Phosphorus. Vitamin D acts as a hormone and increases reabsorption of Calcium and Phosphorus by the kidneys and increased bone turnover.

Indications:

Prevention and treatment of Vitamin D deficiency states.

Dosage and administration:

Adult: Treatment of Vitamin D Deficiency: 40000 IU per week for 7 weeks, followed by maintenance therapy (800-2000 IU/day). Follow-up 25(OH) D measurements should be made approximately 3 to 4 months after initiating maintenance therapy to confirm that the target level has been achieved.

Prevention of Vitamin D deficiency: 20000 IU/Month.

Children: Treatment of Vitamin D deficiency (12-18 years): 20000IU once every 2 weeks for 6 weeks.

Prevention of Vitamin D deficiency (12-18 years): 20000IU once every 6 weeks.

Route of administration: Should be swallowed by mouth with plenty of water.

Contraindications:

Hypersensitivity to any of the components, hypercalcaemia resulting from overdose of Vitamin D, hyperparathyroidism, bone metastases, severe renal insufficiency, severe hypercalciuria, renal calculi etc.

Warnings & precaution:

In presence of mild hypercalciuria, careful monitoring with reduction of dose may be needed. Plasma and serum Calcium level should be monitored in mild to moderate renal impairment and also in case of long term use. Patients with renal stone or with such previous, history should also take precaution.

Cholecalciferol may increase the risk of digitalis toxicity (arrhythmia). Cholecalciferol should also be prescribed with caution in patients with sarcoidosis.

Side effects:

Common: Hypercalcemia due to prolong use has been commonly reported.

Rare: Flatulence, diarrhea, constipation, upper GI discomfort etc. are rare manifestation.

Use in pregnancy & lactation:

Pregnancy: There is no evidence to suggest that vitamin D is teratogenic in humans even at very high doses. Cholecalciferol should be used during pregnancy only if the benefits outweigh the potential risk to the fetus.

Lactation: It should be assumed that exogenous cholecalciferol passes into the breast milk. In view of the potential for hypercalcemia in the mother and for adverse reactions from cholecalciferol in nursing infants, mothers may breastfeed while taking cholecalciferol, provided that the serum Calcium levels of the mother and infant are monitored.

Use in children:

Cholecalciferol capsules should not be given to children under the age of 12.

Drug interactions:

With Medicine: Cholecalciferol is known to interact with Carbamazepine, Dactinomycin, Diuretics, Fosphenytoin, Miconazole, Phenobarbital, Phenytoin, Primidone.

With Food & Others: Mineral oil containing foods interferes with the absorption of fat-soluble vitamins, including vitamin D preparations.

Overdose:

At high doses it may result in nausea, vomiting, dizziness, anorexia, abdominal cramps, headache, constipation etc. Treatment includes cessation of therapy and adequate rehydration.

Storage:

Store in a cool and dry place below 30° C, protect from light. Keep out of the reach of children.

Packing:

3D™ 2000 IU Tablet: Each box contains 30 tablets in Alu-Alu blister packs.

3D™ 20000 IU Capsule: Each box contains 10 capsules in Alu-Alu blister packs.

3D™ 40000 IU Capsule: Each box contains 7 capsules in Alu-Alu blister packs.