

# Ortho-D3

Cholecalciferol

## Presentation

**Ortho-D3 1000 IU Tablet:** Each film-coated tablet contains Cholecalciferol USP (as Vitamin D3) 1000 IU.

**Ortho-D3 2000 IU Tablet:** Each film-coated tablet contains Cholecalciferol USP (as Vitamin D3) 2000 IU.

**Ortho-D3 40000 IU Capsule:** Each capsule contains Cholecalciferol USP (as Vitamin D3) 40000 IU.

**Ortho-D3 100 ml Oral Solution:** Each 5 ml Oral Solution contains Cholecalciferol USP (as Vitamin D3) 1000 IU.

## Description

Vitamin D is essential for normal bone growth and development and to maintain bone density. 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.

## Indication

Prevention and treatment of Cholecalciferol (Vitamin D3) deficiency states.

## Dosage & Administration

### Adults:

For Tablet:

**1000 IU** (1-2 tablets) daily. Take the medicine with food or within 1 hour after a meal.

**2000 IU** (1 tablet) daily. Take the medicine with food or within 1 hour of a meal

**Treatment of Vitamin D deficiency:** 40000 IU/week for 7 weeks, followed by maintenance therapy 2000 IU/day or 1000 IU/day or as directed by registered physician.

Take the medicine with food or within 1 hour after meal.

Prevention of Vitamin D deficiency: 20000 IU/Month.

### Children:

Treatment of Vitamin D deficiency, 12-18 years: 20000 IU, once every 2 weeks for 6 weeks. Prevention of Vitamin D deficiency, 12-18 years: 20000 IU, once every 6 weeks.

### Oral Solution:

For patients with risk of Cholecalciferol deficiency:

Up to 1 Year: 400 IU/day (2 ml), >1 Year: 600 IU/day (3 ml)

For Cholecalciferol deficient patients:

Up to 1 Year : 2000 IU/day for 6 weeks (10 ml)

1-18 Years : 2000 IU/day for 6 weeks (10 ml)

## Side effects

Generally all nutritional supplements are considered to be safe and well tolerable. However, few side-effects can generally occur including hypercalcaemia syndrome or Calcium intoxication (depending on the severity and duration of hypercalcaemia), occasional acute symptoms include anorexia, headache, nausea, vomiting, abdominal pain or stomach ache and constipation with the administration of Cholecalciferol.

## Precautions

People with the following conditions should exercise caution when considering taking vitamin D supplements:

\* High blood Calcium or Phosphorus level

\* Heart problems

\* Kidney disease

Vitamin D must be taken with adequate amounts of both Calcium and Magnesium supplementation. When Calcium level is low (due to insufficient vitamin D and calcium intake), the body activates the parathyroid gland, which produces PTH (parathyroid hormone). This hormone kick starts vitamin D hormone production and assists removal of Calcium from the bones to be used in more important functions such as neutralizing body acidity.

## Contraindications

Cholecalciferol is contraindicated in all diseases associated with hypercalcaemia. It is also contraindicated in patients with known hypersensitivity to Cholecalciferol (or medicines of the same class) and any of the constituent excipients. Cholecalciferol is contraindicated if there is evidence of vitamin D toxicity.

## Use in Pregnancy and Lactation

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.

It should be assumed that exogenous Cholecalciferol passes into the breast milk. In view of the potential for hypercalcaemia in the mother and for adverse reactions from Cholecalciferol in nursing infants, mothers may breastfeed while taking Cholecal-

ciferol, provided that the serum Calcium levels of the mother and infant are monitored.

### **Drug-Interactions**

Since Cholecalciferol is one of the most important active metabolites of vitamin D, pharmacological doses of vitamin D and its derivatives should be withheld during treatment with Cholecalciferol to avoid possible additive effects and hypercalcaemia.

Dietary instructions, especially concerning Calcium supplements, should be strictly observed and uncontrolled intake of additional Calcium-containing preparations avoided.

Concomitant treatment with a thiazide diuretic increases the risk of hypercalcaemia. Cholecalciferol dosage must be determined with care in patients undergoing treatment with digitalis, as hypercalcaemia in such patients may precipitate cardiac arrhythmias.

Magnesium-containing medicines (e.g. antacids) may cause hypermagnesemia and should therefore not be taken during therapy with Cholecalciferol by patients on chronic renal dialysis.

### **Commercial Pack**

Ortho-D3 1000 IU Tablet: Each box contains 5x10's tablet in Alu-Alu blister strip.

Ortho-D3 2000 IU Tablet: Each box contains 3x10's tablet in Alu-Alu blister strip.

Ortho-D3 40000 IU Capsule: Each box contains 1x10's capsule in blister strip.

Ortho-D3 100 ml Oral Solution: Each amber colored glass bottle contains 100 ml Oral Solution.

*Manufactured by*



For further query on the use of this medicine, consult to a registered Doctor or Pharmacist.