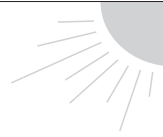


MaxD 20000

Cholecalciferol USP 20000 IU



Composition:

MaxD 20000 IU Capsule: Each capsule contains Cholecalciferol USP 20000 IU.

Descriptions: Vitamin D₃ is the only vitamin that the body can manufacture from sunlight (UVB). Yet, with today's indoor living and extensive use of sunscreens due to concern about skin cancer, we are now a society with millions of individuals deficient in life-sustaining bone building and immune modulating 1,25-dihydroxy Vitamin D₃.

Vitamin D₃ 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 D₃ acts as a hormone and increases reabsorption of Calcium and Phosphorus by the kidneys and increases bone turnover.

Vitamin D₃ is not just for bone health, but also plays a critical role in the health of the muscle, brain and nervous systems, cardiovascular and immune systems. It also supports the health of mother and child during pregnancy and lactation.

Vitamin D₃ reduces the incidence & severity of bacterial infections; improves lung function, especially in former smokers; reduces the risk of cancer (breast, colorectal and others); inhibits skin cell growth associated with psoriasis and other skin conditions; helps to maintain adequate insulin levels for people with type 2 diabetes.

Vitamin D₃ is produced when sunlight converts cholesterol in the skin into a form of Vitamin D₃ called Calcidiol. Then the liver hydroxylates Calcidiol into a form called Calcidiol (25-hydroxy Vitamin D₃). The kidneys then hydroxylate Calcidiol into the active form of Vitamin D₃ called Calcitriol (1,25-dihydroxy Vitamin D₃), which acts as a hormone.

Calcidiol, the inactive form of Vitamin D₃ is circulated and stored in the body. Virtually every cell in the human body has receptors for Vitamin D₃ because it is not just a Vitamin, but also a hormone. As a hormone, it controls phosphorus, calcium, and bone metabolism and neuromuscular function. Ultimately it regulates cellular production of important proteins and peptides. Vitamin D₃ also affects the expression of many genes, including ones that are key factors in the development of cancer.

Pharmacology: The active form of Vitamin D₃, Calcitriol, exerts its effect by binding to the Vitamin D₃ receptors (VDRs) which are widely distributed through many body tissues. Vitamin D₃ has a half life of approximately 50 days as it is fat soluble. Vitamin D₃ is absorbed in the small intestine and bound to specific α-globulins and transported to the liver where it is metabolised to 25-hydroxy Vitamin D₃ (Calcidiol). A second hydroxylation to 1,25-dihydroxy Vitamin D₃ (Calcitriol) occurs in the kidney. This metabolite is responsible for the vitamin's ability to increase the absorption of calcium. Non-metabolised Vitamin D₃ is stored in tissues such as fat and muscle. Vitamin D₃ is eliminated via faeces and urine.

Indications: Vitamin D₃ deficiency can occur in people whose exposure to sunlight is limited and in those whose diet is deficient in vitamin D₃. Vitamin D₃ is essential for the effective calcium and phosphate absorption required for healthy bones and teeth, preventing rickets, osteomalacia and osteoporosis. High doses are also very effective in institutionalized or hospitalized patients. Vitamin D₃ is important during pregnancy and breast-feeding as it is an essential nutrient for a growing infant. But Vitamin D₃ in such high doses may cause toxicity and therefore should be taken only if prescribed by a physician.

Dosage & Administration:

Adults:

Treatment of Cholecalciferol deficiency: 20000 IU twice every week for 7 weeks, followed by maintenance therapy equivalent to 1400 - 2000 IU/day.

Follow-up 25(OH)D measurements should be made approximately three to four months after initiating maintenance therapy to confirm that the target level has been achieved

Prevention of Cholecalciferol deficiency: 20000 IU every 4 weeks (1 capsule), higher doses may be required in certain populations.

Children:

Treatment of Cholecalciferol deficiency (12-18 years): 20000 IU (1 capsule) once every 2 weeks for 6 weeks.

Prevention of Cholecalciferol deficiency (12-18 years): 20000 IU (1 capsule) every 6 weeks.

Use in Pregnancy: Vitamin D₃ is essential during pregnancy. But Vitamin D₃ being fat soluble, high doses can be reached in the body tissue causing overdose and toxicity. So in case of pregnancy, such high doses shall be taken only with medical supervision.

Use in Lactation: Cholecalciferol and its metabolites are excreted in breast milk. Overdose in infants induced by nursing mothers has not been observed. Yet precaution should be taken by lactating mothers before taking high doses of Vitamin D₃.

Pediatric Use: Cholecalciferol 20000 IU capsules should not be given to infants and children under the age of 12.

Side effects: Symptoms rarely include anorexia, lassitude, nausea & vomiting, diarrhea, constipation, weight loss, polyuria, sweating, headache, thirst, vertigo, and raised concentrations of calcium and phosphate in plasma and urine.

Precautions: Plasma-calcium concentration should be monitored at intervals in patients receiving high doses of Vitamin D₃, in renal impairment, and during pregnancy & lactation. People using Digoxin and Thiazide Diuretics should consult a health care practitioner before supplementing with Vitamin D₃. People with liver or kidney disease, primary hyperthyroidism, lymphoma, tuberculosis and granulomatous disease should consult a health care practitioner before supplementing with Vitamin D₃. High doses of Vitamin D₃ should be prescribed with caution to patients suffering from sarcoidosis.

Contraindications: Vitamin D₃ is contraindicated in all diseases associated with hypercalcaemia. It is also contraindicated in patients with known hypersensitivity to Vitamin D₃ (or medicines of the same class) and any of the excipients. It is contraindicated if there is evidence of Vitamin D₃ toxicity.

Drug Interactions: Antacids (Magnesium-containing), Phenytoin, Phenobarbital, Cholestyramine, Cholestipol, Digoxin, Thiazide Diuretics. Many drugs cause Vitamin D₃ deficiencies because they interfere with the absorption and metabolism of Vitamin D₃, and includes Cholestyramine, Cholistipol, Phenytoin, Phenobarbital, Orlistat, and Mineral Oil. Also, Corticosteroids, such as Prednisolone increase the need for Vitamin D₃.

Overdose: Being fat soluble, Vitamin D₃ overdose can cause toxicity. A daily intake of more than 10000 IU can lead to toxicity. Chronic overdoses can lead to vascular and organ calcification as a result of hypercalcaemia. Treatment should consist of stopping all intakes of Vitamin D₃ and rehydration.

Storage: Store in a cool and dry place, protect from light. Do not freeze.

Packaging: MaxD 20000 IU Capsule: Each box contains 2x8's capsule in blister pack.

Manufactured by



Ziska Pharmaceuticals Ltd.
Kaliakoir, Gazipur, Bangladesh