

D-Fill™

Cholecalciferol (Vitamin D₃)

Composition

D-Fill™ 2000 Capsule: Each Liquid Filled Hard Gelatin capsule contains Cholecalciferol (Vitamin D₃) USP 2000 IU

D-Fill™ 20000 Capsule: Each Liquid Filled Hard Gelatin capsule contains Cholecalciferol (Vitamin D₃) USP 20000 IU

D-Fill™ 40000 Capsule: Each Liquid Filled Hard Gelatin capsule contains Cholecalciferol (Vitamin D₃) USP 40000 IU

Description

D-Fill™ is a preparation of Cholecalciferol, a synthetic form of Vitamin D₃. Cholecalciferol helps to increase the reabsorption of calcium and phosphorus in our body.

Pharmacology

Cholecalciferol (Vitamin D₃) is essential for normal bone growth, development and to maintain bone density. Cholecalciferol (Vitamin D₃) acts as a hormone and increases reabsorption of calcium and phosphorus by the kidneys and increased bone turnover.

Indications

- Prevention and treatment of Cholecalciferol deficiency condition.
- Hypoparathyroidism
- Vitamin D resistant rickets

Dosage & Administration

Adults: Treatment of Cholecalciferol deficiency: 40000-50000 IU/week for 7 weeks, followed by maintenance therapy (1400-2000 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 once in every month.

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

Contraindications

- Hypersensitivity to Cholecalciferol or any of the excipients in the product
- Hypervitaminosis D
- Nephrolithiasis
- Severe renal impairment

Precautions

Cholecalciferol should be used with caution in patients with impairment of renal function and the effect on calcium and phosphate levels should be monitored. Caution is required in patients receiving treatment for cardiovascular disease as the administration of Cholecalciferol may increase the risk of digitalis toxicity (arrhythmia). Cholecalciferol should also be prescribed with caution in patients with sarcoidosis. There is no clear evidence for causation between Cholecalciferol supplementation and renal stones, but the risk is plausible, especially in the context of concomitant calcium supplementation. Medical supervision is required whilst on treatment to prevent hypercalcemia.

Side Effects

Metabolism and nutrition disorders: Uncommon (a 1/1000 to <1/100): Hypercalcemia and hypercalciuria. Gastrointestinal disorders: Rare (a 1/10000 to <1/1000): Constipation, flatulence, bloating, abdominal distension, nausea, abdominal pain and diarrhea. Skin and subcutaneous tissue disorders: Rare (a 1/10000 to < 1/1000): Pruritus, rash and urticaria.

Use in Pregnancy & Lactation

Pregnancy

Studies have shown safe use of doses up to 4000 IU during pregnancy. The recommended daily intake for pregnant women is 400 IU, however, in women who are considered to be Cholecalciferol deficient, a higher dose may be required. During pregnancy, women should follow the advice of their medical practitioner as their requirements may vary depending on the severity of their disease and their response to treatment.

Lactation

Cholecalciferol and its metabolites are excreted in breast milk. Overdose in infants induced by nursing mothers has not been observed; however, when prescribing additional Cholecalciferol to a breast-fed child the practitioner should consider the dose of any additional Cholecalciferol given to the mother.

Drug Interactions

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

Overdose

Symptoms: anorexia, headache, vomiting, constipation, dystrophy (weakness, loss of weight), sensory disturbances, possibly fever with thirst, polyuria, dehydration, apathy, and urinary tract infections. Hypercalcemia occurs, with metastatic calcification of the renal cortex, myocardium, lungs and pancreas.

Storage

Store below 30°C & dry place, away from light. Keep out of the reach of children.

Packing

D-Fill™ 2000 Capsule: Each box contains 3 blister packs with each blister of 10 capsules.

D-Fill™ 20000 Capsule: Each box contains 1 blister pack with each blister of 10 capsules.

D-Fill™ 40000 Capsule: Each box contains 1 blister pack with each blister of 10 capsules.

Manufactured by:

 **GENERAL**
Pharmaceuticals Ltd.
Mouchak, Kaliakair, Gazipur, Bangladesh

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