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CHOLECALCIFEROL [VITAMIN D3] USP

Compositions:
D-2000 Tablet: Each Tablet Contains Cholecalciferol (Vitamin D3) USP 2000 IU. D-20000 Capsule: Each Capsule Contains Cholecalciferol (Vitamin D3) USP 20000 IU. D-40000 Capsule: Each Capsule Contains Cholecalciferol (Vitamin D3) USP 40000 IU.

Pharmacology:
The active form of Vitamin D3 “calcitriol”, exerts its effect by binding to the Vitamin D receptors (VDRs) which are widely distributed through many body tissues. Vitamin D3 is absorbed in the small intestine and bound to specific-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 vitamins 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.

Dosage And Administration:
2000 IU (1 tablet) daily with food or within 1 hour after a meal. Prevention of Vitamin D3 deficiency: Starting dose of 1 capsule (20000 IU) once a month. As an adjunct to specific therapy for osteoporosis: 1 capsule (20000 IU) once a month. Treatment of vitamin D3 deficiency: 40000 IU once weekly for 7 weeks, followed by maintenance therapy such as 2-3 capsuls per month or 1400-2000 IU/day or as directed by the registered physician.

Contraindications:
It is contraindicated in patients with known hypersensitivity to Vitamin D3 or any other components of this product.

Warning And Precaution:
Vitamin D3 20000 IU & Vitamin D3 40000 IU Capsules should be used with caution in patients with impaired renal function, impaired renal calcium and phosphate excretion, a tendency to form kidney stones (calculi), hypercalcemia, hypercalciuria.

Side Effects:
The side effects of this product are hypercalcaemia, hypercalciuria, pruritus, rash, urticaria, constipation, flatulence, nausea, abdominal pain, chronic diarrhoea (increased urination, increased thirst, loss of appetite, weight loss, kidney stones, kidney calcification, calcification may in tissues outside the bone) episodes occur.

Use in Pregnancy and Lactation:
This high strength formulation is not recommended in Pregnancy and Lactation.

Drug Interaction:
Concomitant treatment with phenytoin or barbiturates, glucocorticoids can decrease the effect of Vitamin D3. Simultaneous treatment with ion exchange resins such as cholestyramine or laxatives such as paraffin oil may reduce the gastrointestinal absorption of Vitamin D3. The cytotoxic agent actinomycin and imidazole antifungal agents interfere with Vitamin D3 activity.

Overdosage:
Being fat soluble, Vitamin D3 overdose can cause 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:
Keep below 30° C , store at a cool & dry place, protect from light & moisture. Keep the medicine out of reach of children.

Packing:
D-2000 Tablet: Each box contains 5x10 tablets in blister pack. D-20000 Capsule: Each box contains 1x10 capsules in blister pack. D-40000 Capsule: Each box contains 1x10 capsules in blister pack.

Manufactured By:
The IBN SINA Pharmaceutical Industry PLC.
Shafipur, Gazipur, Bangladesh.