D 360

For the use of a Registered Medical Practitioner or Hospital or a Laboratory only

Abbreviated Prescribing information for **D 360** [Cholecalciferol I.P. 60,000 I.U.] [Please refer the complete prescribing information available at www.torrentpharma.com] **PHARMACOLOGICAL PROPERTIES:** The *in vivo* synthesis of the major biologically active metabolites of vitamin D occurs in two steps. The first hydroxylation takes place in the liver (to 25-hydroxy vitamin D) and the second in the kidneys (to 1, 25-dihydroxy- vitamin D). 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. Parathyroid hormone is responsible for the regulation of this metabolism in the kidneys. **INDICATION**: For the treatment of vitamin D deficiency in: Hypophosphataemic rickets and osteomalacia, Post gastrectomy and intestinal malabsorption osteomalacia, Osteomalacia associated with prolonged use of anticonvulsants and other hepatic microsomal enzyme-inducing drugs, Osteomalacia associated with hepatobiliary disorders. **DOSAGE AND ADMINISTRATION**: D 360 Granules should be taken as one fourth of 1 sachet with milk or as directed by the Physician. **CONTRAINDICATION:** This formulation contraindicated in the patient known to be hypersensitive (allergic) to Vitamin D used in this formulation. In patients with hypercalcemia, malabsorption syndrome, abnormal sensitivity to the toxic effects of vitamin D, and hypervitaminosis D. **WARNINGS & PRECAUTIONS**: Hypersensitivity to vitamin D may be one etiologic factor in infants with idiopathic hypercalcemia. In these cases, vitamin D must be strictly restricted. Vitamin D should not be given to patients with hypercalcemia. It should be used with caution in infants, who may have increased sensitivity to its effects, and patients with renal impairment or calculi, or heart disease, who might be at increased risk of organ damage if hypercalcemia occurred. Similar monitoring is recommended in infants if they are breast fed by mothers receiving pharmacological doses of vitamin D. Hypercalcemia during pregnancy may produce congenital disorders in the offspring, and neonatal hypoparathyroidism. Vitamin D is distributed into breast milk, and its concentration appears to correlate with the amount of vitamin D in the serum of exclusively breast-fed infants. The infant be closely monitored for hypercalcemia or clinical manifestations of vitamin D toxicity if the mother is taking pharmacological doses of vitamin D. **DRUG INTERACTIONS**: There is an increased risk of hypercalcemia if vitamin D is given with thiazide diuretics, calcium, or phosphate. Some antiepileptic's may increase vitamin D requirements (e.g. carbamazepine, phenobarbital, phenytoin, and primidone). Rifampicin and isoniazid may reduce the effectiveness of vitamin D. Corticosteroids may counteract the effect of vitamin D. Ketoconazole may inhibit the metabolism of paricalcitol and these drugs should be used with caution together; care should be taken when using paricalcitol with other potent inhibitors of the cytochrome P450 isoenzyme CYP3A4. **ADVERSE REACTIONS**: Excessive intake of vitamin D leads to the development of hyperphosphataemia or hypercalcaemia. Impairment of renal function with polyuria, nocturia, polydipsia, hypercalciuria, reversible azotemia, hypertension, nephrocalcinosis, generalized vascular calcification, or irreversible renal insufficiency which may result in death. Mental retardation, widespread calcification of the soft tissues, including the heart, blood vessels, renal tubules, and lungs. Bone demineralization (osteoporosis) in adults occurs concomitantly. Decline in the average rate of linear growth and increased mineralization of bones in infants and children (dwarfism), vague aches, stiffness, and weakness. Nausea, anorexia, constipation, Mild acidosis, anemia, weight loss.

MARKETED BY:

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