D 360

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

Abbreviated Prescribing information for D 360 Capsule (Cholecalciferol Capsules) [Please refer the complete prescribing information available at <u>www.torrentpharma.com</u>]

PHARMACOLOGICAL PROPERTIES: Cholecalciferol is the naturally occurring form of 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.

INDICATION: Vitamin D deficiency in Hypophosphataemic rickets, osteomalacia, postgastrectomy, intestinal malabsorption osteomalacia, osteomalacia associated with prolonged use of anticonvulsants/other hepatic microsomal enzyme-inducing drugs/hepatobiliary disorders. As an adjuvant in the management of chronic disease state in which vitamin D deficiency is Suspected such as CVD, Diabetes, Cancer (breast, prostate and colon), infectious diseases, TB and COPD.

DOSAGE AND ADMINISTRATION: For oral administration. A dose of 400 units daily is generally sufficient in adults for the prevention of simple deficiency states; 800 units daily is recommended in those whose exposure to sunlight is limited, in those whose diet is deficient in vitamin D, and in housebound or institutionalized elderly people. Deficiency due to malabsorption states or liver disease often requires higher doses for treatment, of up to 40 000 units daily. Doses of up to 200 000 units daily may be used in the treatment of hypocalcaemia due to hypoparathyroidism.

CONTRAINDICATION: Hypersensitivity to Vitamin D, hypercalcemia, malabsorption syndrome, abnormal sensitivity to the toxic effects of vitamin D, hypervitaminosis D.

WARNINGS & PRECAUTIONS: Hypercalcaemia, use with caution in infants, renal impairment or calculi, or heart disease, who might be at increased risk of organ damage if hypercalcaemia occurred, Increased phosphate level, Vitamin D distributed in to breast milk and thus breast feed infants should be monitored.

DRUG INTERACTIONS: Interacts with thiazide diuretics, calcium, or phosphate, anti-convulsants, Rifampicin, isoniazid, Corticosteroids, Ketoconazole, CYP 3A4 inhibitors, and Mineral oils.

ADVERSE REACTIONS: Hyperphosphataemia, hypercalcaemia, hypercalciuria, ectopic calcification, renal/cardiovascular damage, anorexia, lassitude, nausea, vomiting, Skin irritation or contact dermatitis, constipation or diarrhoea, polyuria, nocturia, sweating, headache, thirst, somnolence, vertigo. mental retardation, dwarfism, osteoporosis, weight loss, mild acidosis, Stiffness, weakness, soft tissue calcification, impaired renal function.

MARKETED BY:

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