

D 360 DROPS

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

Abbreviated Prescribing information for D 360 Drops [Cholecalciferol (Vitamin D3) Oral Drops]
[Please refer the complete prescribing information available at www.torrentpharma.com]

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: For 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: Exclusively breastfed infants and those consuming less than 1 L of infant formula/day should receive 400 IU/day of an oral liquid vitamin D product. Preterm infants should receive 400 to 800 IU of vitamin D (10 to 20 mcg) per day to compensate for decreased placental transfer in utero and decreased gastrointestinal absorption after birth. For treatment of documented vitamin D deficiency, infants may be given 1,000 to 2,000 IU/day (25 to 50 mcg) and older children may be given up to 5,000 IU/day (125 mcg) for 2 to 3 months. A high-dose short-course regimen providing a total of 100,000 to 600,000 IU (2.5 to 15 mg) over 1 to 5 days has been suggested for patients who might not adhere to longer regimens.

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:



TORRENT PHARMACEUTICALS LTD.

Torrent House, Off Ashram Road,
Ahmedabad-380 009, INDIA

IN/D 360 DROPS /FEB 2015/01/AbPI

(Additional information is available on request)