D3-HIGH SACHET/ D-360

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

Abbreviated Prescribing information for D3-HIGH SACHET/ D-360 [Cholecalciferol I.P. (Vitamin D3) 60,000 I.U.]

[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: 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.

INDICATIONS: For the treatment of vitamin D deficiency in: Hypophosphataemic rickets and osteomalacia, Postgastrectomy and intestinal malabsorption osteomalacia, Osteomalacia associated with prolonged use of anticonvulsants and other hepatic microsomal enzyme-inducing drugs, and Osteomalacia associated with 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 the treatment of simple nutritional deficiencies cholecalciferol is generally preferred. They are usually given orally. 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. 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 hypercalcaemia. 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 hypercalcaemia occurred. Plasma phosphate concentrations should be controlled during vitamin D therapy to reduce the risk of ectopic calcification. It is advised that patients receiving pharmacological doses of vitamin D should have their plasma-calcium concentration monitored at regular intervals, especially initially or if symptoms suggest toxicity. Similar monitoring is recommended in infants if they are breast fed by mothers receiving pharmacological doses of vitamin D.

DRUG INTERACTIONS: There is an increased risk of hypercalcaemia if vitamin D is given with thiazide diuretics, calcium, or phosphate. Plasma-calcium concentrations should be monitored in such situations. Some antiepileptics 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. Mineral oil interferes with the absorption of fat-soluble vitamins, including vitamin D preparations.

ADVERSE REACTIONS: Excessive intake of vitamin D leads to the development of hyperphosphataemia or hypercalcaemia. Associated effects of hypercalcaemia include hypercalciuria, ectopic calcification, and renal and cardiovascular damage. Symptoms of overdosage include anorexia, lassitude, nausea and vomiting, constipation or diarrhoea, polyuria, nocturia, sweating, headache, thirst, somnolence, and vertigo. Interindividual tolerance to vitamin D varies considerably; infants and children are generally more susceptible to its toxic effects. The vitamin should be withdrawn if toxicity occurs. It has been stated that vitamin D dietary supplementation may be detrimental in persons already receiving an adequate intake through diet and exposure to sunlight, since the difference between therapeutic and toxic concentrations is relatively small. The most potent forms of vitamin D, such as alfacalcidol and calcitriol, might reasonably be expected to pose a greater risk of toxicity; however, their effects are reversed rapidly on withdrawal. Hypersensitivity reactions have occurred. Skin irritation or contact dermatitis has been reported with topical preparations. *Hypercalcaemia:* Vitamin D is the most likely of all vitamins to cause overt toxicity. Doses of 60000 units daily can cause hypercalcaemia, with muscle weakness, apathy, headache, anorexia, nausea and vomiting, bone pain, ectopic calcification, proteinuria, hypertension, and cardiac arrhythmias. Chronic hypercalcaemia can lead to generalised vascular calcification, nephrocalcinosis, and rapid deterioration of renal function. Hypercalcaemia has been reported in a patient after brief industrial exposure to colecalciferol. A study in children treated for renal osteodystrophy has provided some evidence that hypercalcaemia may occur more frequently with calcitriol than with ergocalciferol. Another such study has suggested that vitamin D has nephrotoxic properties independent of the degree of induced hypercalcaemia, and that the decline in renal function may be more marked with calcitriol. Topical calcitriol may affect calcium homoeostasis, and hypercalcaemia has been reported in some studies. Hypervitaminosis D is characterized by effects on the following organ system: *Renal***:** 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. *CNS:* Mental retardation. *Soft Tissues:* Widespread calcification of the soft tissues, including the heart, blood vessels, renal tubules, and lungs. *Skeletal:* 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. *Gastrointestinal:* Nausea, anorexia, constipation. *Metabolic:* Mild acidosis, anemia, weight loss.

MARKETED BY:

TORRENT PHARMA

Torrent Pharmaceuticals Limited.

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(Additional information is available on request)