TORFLASH

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

Abbreviated Prescribing information for TORFLASH (Cholecalciferol granules 60,000 IU) [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Cholecalciferol is the naturally occurring form of vitamin D. It is produced from 7- dehydrocholesterol, a sterol present in mammalian skin, by ultraviolet irradiation.

INDICATION: Vitamin D compounds are used in the treatment and prevention of vitamin D deficiency states and hypocalcaemia in disorders such as hypoparathyroidism and secondary hyperparathyroidism.

DOSAGE AND 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: Contraindicated in the patient known to be hypersensitive (allergic) to vitamin D and other ingredients, in patients with hypercalcemia, malabsorption syndrome, abnormal sensitivity to the toxic effects of vitamin D, and hypervitaminosis D.

WARNINGS & PRECAUTIONS: Used with cautions in hypersensitivity to vitamin D, in infants with idiopathic hypercalcemia, patients with hypercalcaemia, renal impairment or calculi, or heart disease. Plasma phosphate concentrations should be controlled. 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 INTERACTION: Thiazide diuretics, calcium, or phosphate, carbamazepine, phenobarbital, phenytoin, primidone, rifampicin and isoniazid, corticosteroids, ketoconazole.

ADVERSE REACTIONS: Hyperphosphataemia or hypercalcaemia, hypercalciuria, ectopic calcification, renal and cardiovascular damage, anorexia, lassitude, nausea and vomiting, constipation or diarrhoea, polyuria, nocturia, sweating, headache, thirst, somnolence, and vertigo, Skin irritation or contact Dermatitis, hypersensitivity reaction, muscle weakness, apathy, headache, bone pain, ectopic calcification, proteinuria, hypertension, and cardiac arrhythmias. Impairment of renal function with polyuria, nocturia, polydipsia, reversible azotemia, nephrocalcinosis, generalized vascular calcification, mental retardation, widespread calcification, bone demineralization (osteoporosis), constipation, mild acidosis, anemia and weight loss.

MARKETED BY:

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(Additional information is available on request)