CALFLASH 500

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

Abbreviated Prescribing information for CALFLASH 500[Calcium 500mg with Vitamin D3 250mg Tablets U.S.P] [Please refer the complete prescribing information available at <u>www.torrentpharma.com</u>] PHARMACOLOGICAL PROPERTIES: Vitamin D3 increases the intestinal absorption of calcium. Administration of calcium and Vitamin D3 counteracts the increase of parathyroid hormone (PTH) which is caused by calcium deficiency and which causes increased bone resorption. **INDICATION**: To be used during calcium deficiency, supplementation of calcium during growth, pregnancy, lactation or as directed by the Physician. It may be used as an adjunct to specific therapy for osteoporosis or as a therapeutic supplement in established osteomalacia, pregnant patients at high risk of needing such a therapeutic supplementation or malnutrition when dietary intake is less than that required. DOSAGE AND ADMINISTRATION: Adjunctive therapy in osteoporosis: One tablet 2-3 times per day, Calcium and Vitamin D3 deficiency: In adults one tablet 2-3 times per day, in children one tablet 2-3 times per day. During pregnancy the daily intake should not exceed 1500 mg calcium and 600 IU Vitamin D3. CONTRAINDICATION: Diseases and/or conditions resulting in hypercalcemia and/or hypercalciuria, nephrolithiasis, hypervitaminosis D and hypersensitivity to the active substances or to any of the excipients. WARNINGS & PRECAUTIONS: Calflash should not be used in patients with severe renal impairment. In case of hypercalcaemia or signs of impaired renal function, the dose should be reduced or the treatment discontinued. Vitamin D3 should be used with caution in patients with impairment of renal function. During long-term treatment, serum calcium levels should be followed and renal function should be monitored through measurement of serum creatinine. Should be prescribed with caution to patients suffering from sarcoidosis. Used with caution in immobilized patients with osteoporosis due to the increased risk of hypercalcaemia. Caution should be exercised while prescribing Cholecalciferol and other medicinal products containing Vitamin D3 or nutrients (such as milk). DRUG INTERACTIONS: Thiazide diuretics reduce the urinary excretion of calcium. Cholestyramine or laxatives such as paraffin oil may reduce the gastrointestinal absorption of Vitamin D3. Calcium carbonate may interfere with the absorption of concomitantly administered tetracycline preparations. Hypercalcaemia may increase the toxicity of cardiac glycosides during treatment with calcium and Vitamin D3. The efficacy of levothyroxine can be reduced by the concurrent use of calcium. The absorption of quinolone antibiotics may be impaired if administered concomitantly with calcium. The patient should not take calcium products within two hours of eating foods high in oxalic acid and phytic acid. ADVERSE REACTIONS: Hypercalcemia, hypercalciuria, milk-alkali syndrome, gastrointestinal disorders, constipation, dyspepsia, flatulence, nausea, abdominal pain, diarrhea, pruritus, rash and urticaria.

MARKETED BY:



TORRENT PHARMACEUTICALS LTD. Torrent House, Off Ashram Road, Ahmedabad-380 009, INDIA IN/ CALFLASH 500mg /JUN-2016/01/ABPI (Additional information is available on request)