SHELCAL MOM

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

Abbreviated Prescribing information for SHELCAL MOM (Calcium Carbonate, Pyridoxal 5'-Phosphate, Folic Acid, Vitamin D3, Cyanocobalamin with Docosahexaenoic Acid (DHA) Tablets**)**

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

PHARMACOLOGICAL PROPERTIES:

Mechanism of action:

DOSAGE AND ADMINISTRATION: One tablet once daily or as directed by physician.

CONTRAINDICATION: Hypersensitivity to the active substances or to any of the excipients, diseases and/or conditions resulting in in hypercalcaemia and/or hypercalciuria (e.g. myeloma, bone metastases, primary hyperparathyroidism), Nephrolithiasis, Renal failure, Hypervitaminosis D, Sarcoidosis, Vitamin D overdosage, Long-term therapy is contraindicated in any patient with untreated cobalamin deficiency. This can be untreated pernicious anaemia or other cause of cobalamin deficiency, including lifelong vegetarians. In elderly people, a cobalamin absorption test should be done before long-term therapy. Folate given to such patients for 3 months or longer has precipitated cobalamin neuropathy. No harm results from short courses of folate, Should never be given alone in the treatment of Addisonian pernicious anaemia and other vitamin B_{12} deficiency states because it may precipitate the onset of subacute combined degeneration of the spinal cord, Should not be used in malignant disease unless megaloblastic anaemia owing to folate deficiency is an important complication.

WARNINGS & PRECAUTIONS: During long-term treatment, serum calcium levels should be followed and renal function should be monitored through measurement of serum creatinine. Monitoring is especially important in elderly patients on concomitant treatment with cardiac glycosides or diuretics and in patients with a high tendency to calculus formation. Vitamin D_3 should be used with caution in patients with impairment of renal function and the effect on calcium and phosphate levels should be monitored, patients with severe renal insufficiency. Caution should be exercised when administering folic acid to patients who may have folate dependent tumours. Patients with rare hereditary problems of galactose intolerance, the lapp lactase deficiency or glucose – galactose malabsorption should not take this medicine. Patients with early Leber's disease (hereditary optic nerve atrophy) who were treated with vitamin B_{12} suffered severe and swift optic atrophy. Hypokalemia and sudden death may occur in severe megaloblastic anemia which is treated intensely with vitamin B_{12}.

DRUG INTERACTION: Thiazide diuretics, Systemic corticosteroids, tetracycline, cholestyramine or laxatives, bisphosphonate or sodium fluoride, levothyroxine, quinolone antibiotics, phenytoin, primidone, phenobarbital, sodium valproate, carbamazepine and the barbiturates, Trimethoprim or sulphonamides, Methotrexate and trimethoprim, Fluorouracil, Para-aminosalicylic acid, colchinine, biguanides, neomycin, cholestyramine, potassium chloride, methyldopa, and cimetidine, chloramphenicol, levodopa.

ADVERSE REACTIONS: Hypercalcaemia and hypercalciuria, Milk-alkali syndrome, Constipation, dyspepsia, flatulence, nausea, abdominal pain and diarrhoea. Skin and subcutaneous disorders Rare: Pruritus, rash and urticarial, anemia, cough, CNS depression, drowsiness, headache, heart damage, lassitude (weakness, exhaustion), liver damage, narcosis, reproductive effects and teratogenic effects, Anorexia, nausea, abdominal distension and

flatulence, Allergic reactions, comprising erythema, rash, pruritus, urticaria, dyspnoea, and anaphylactic reactions (including shock), Anaphylactic reaction, Acne form and bullous eruptions, nausea and headaches.

Marketed BY:

TORRENT PHARMACEUTICALS LTD.

IN/ SHELCAL MOM 500 mg, 2.5 mg, 294 mcg, 400 IU, 1.2 mcg, 150 mg/JAN-21/01/ABPI
(Additional information is available on request)