SHELCAL ISO

For the use of a Registered Medical Practitioner or Hospital or a Laboratory only. Abbreviated Prescribing information for SHELCAL ISO (Calcium carbonate, Calcitriol & Soya Isoflavones 40% Soft Gelatin Capsules)

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

PHARMACOLOGICAL PROPERTIES:

Mechanism of action: Calcium Carbonate: Calcium carbonate is a basic inorganic salt that acts by neutralizing hydrochloric acid in gastric secretions. Soya Isoflavones: Isoflavones are selective estrogen receptor modulators that exert estrogenic-like effects under certain experimental conditions. Calcitriol: Calcitriol is the most active known form of vitamin D₃ in stimulating intestinal calcium transport. The defective production of calcitriol in chronic renal failure contributes to the abnormalities of mineral metabolism found in that disorder.

DOSAGE AND ADMINISTRATION: One tablet once daily or as directed by physician. SHELCAL-ISO soft gelatin capsules should be administered orally. Do not open or crush or chew the capsule. Swallow as a whole.

CONTRAINDICATION: Hypersensitivity to the active substance, diseases and/or conditions resulting in hypercalcemia and/or hypercalciuria, for example in hyperparathyroidism, vitamin D overdosage, decalcifying tumours such as plasmacytoma and skeletal metastases, in severe renal failure untreated by renal dialysis and in osteoporosis due to immobilization, renal calculi (nephrolithiasis), if there is evidence of vitamin D toxicity.

WARNINGS & PRECAUTIONS: Calcium Carbonate: In renal insufficiency and condition with cardiac glycosides or diuretics (given under monitoring), during high dose therapy, Patients with rare hereditary problems of fructose intolerance **Calcitriol:** development of hypercalcaemia, All other vitamin D compounds and their derivatives, An abrupt increase in calcium intake as a result of changes in diet, Calcitriol increases inorganic phosphate levels in serum, Immobilised patients.

DRUG INTERACTION: Calcium Carbonate: Thiazide diuretics, Hypercalcaemia **Calcitriol:**Dietary instructions, especially concerning calcium supplements, should be strictly observed, and uncontrolled intake of additional calcium-containing preparations avoided, Concomitant treatment with a thiazide diuretic increases the risk of hypercalcaemia.

ADVERSE REACTIONS: Hypercalcaemia and hypercalciuria, Milk-alkali syndrome (frequent urge to urinate; continuing headache; continuing loss of appetite; nausea or vomiting; unusual tiredness or weakness; hypercalcaemia, alkalosis and renal impairment). Seen usually only in Overdose, Constipation, dyspepsia, flatulence, nausea, abdominal pain and diarrhoea, Pruritus, rash and urticarial.

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IN/SHELCAL-ISO 500, 60 mg, 0.25 mcg/APR-21/01/ABPI

(Additional information is available on request)