

SHELCAL K

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

Abbreviated Prescribing information for Shelcal K Tablets (Calcium carbonate, Calcitriol and Vitamin K₂)

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

PHARMACOLOGICAL PROPERTIES: *Calcium Carbonate:* Calcium preparations are used to prevent or to treat calcium deficiencies, *Calcitriol:* It is the active form of vitamin D₃. Vitamin D is important for the absorption of calcium from the stomach and for the functioning of calcium in the body, *Vitamin K₂:* It helps regulate tissue calcium content.

INDICATION: For the prevention and treatment of osteoporosis in the elderly especially those with or predisposed to vertebral fractures.

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

CONTRAINDICATION: Shelcal K should not be given to patients with hypercalcaemia or evidence of vitamin D toxicity. Vitamin K is contraindicated in patients who are on anticoagulant therapy.

WARNINGS & PRECAUTIONS: Since calcitriol is the most potent metabolite of vitamin D available, vitamin D and its derivatives should be withheld during treatment. In patients undergoing dialysis, who have serum phosphorus levels abnormal, appropriate serum phosphate binders should be used.

DRUG INTERACTIONS: Concomitant use of magnesium containing antacids and calcitriol may to the development of hypermagnesaemia. The effect of calcitriol and absorption of may be interacted with corticosteroids, cholestyramine. It is avoided in patients on digitalis because hypercalcaemia in such patients may precipitate cardiac arrhythmias. It may reduce the response of verapamil and other calcium channel blockers. Oestrogens may increase calcium absorption. Calcium may prevent absorption of etidronate. Calcium carbonate may reduce absorption of fluoroquinolones and antagonized the effect of gallium. Phenytoin decreases the bioavailability of calcium and phenytoin. Calcium may also decrease the absorption of tetracyclines. Absorption of vitamin K may be decreased with the use of drugs such as cholestyramine, colestipol, orlistat, and substances such as mineral oil and the fat substitute, olestra.

ADVERSE REACTIONS: Vitamin D intoxication, hypercalcaemia, weakness, headache, somnolence, nausea, vomiting, dry mouth, constipation, muscle pain bone pain and metabolic taste. polyuria, polydipsia, anorexia, weight loss, nocturia, conjunctivitis (calcific), pancreatitis, photophobia, rhinorrhea, pruritus, hyperthermia, decreased libido, elevated BUN, albuminuria, hypercholesterolaemia, elevated SGOT and SGPT, ectopic calcification, hypertension, cardiac arrhythmias and rarely, overt psychosis and allergic reaction.

MARKETED BY:

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(Additional information is available on request)