GEMITROL

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

Abbreviated Prescribing information for Gemitrol (Calcitriol, Calcium Carbonate and Zinc Capsules) [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Gemitrol soft gelatin capsule is a combination of Calcitriol, elemental Calcium which is derived from Calcium Carbonate and Zinc.

INDICATIONS: For the treatment of hypocalcaemia and/or osteoporosis.

DOSAGE AND ADMINISTRATION: The recommended dose is one capsule of Gemitrol daily. Gemitrol Capsules should be administered orally.

CONTRAINDICATIONS: Gemitrol should not be given to patients with hypercalcaemia or evidence of vitamin D toxicity. Use of Gemitrol Capsules in patients with known hypersensitivity to Gemitrol Capsules or any of the inactive ingredients is contraindicated.

WARNINGS & PRECAUTIONS: Since calcitriol is the most potent metabolite of vitamin D available, other preparations of vitamin D and its derivatives should be withheld during treatment. Excessive dosage of this combination may induce hypercalcaemia and in some instances hypercalciuria. Calcitriol increases inorganic phosphate levels in serum. While this is desirable in patients with hypophosphatemia, caution is called for in patients with renal failure because of the danger of ectopic calcification. Magnesium - containing preparations (eg, antacids) and calcitriol should not be used concomitantly in patients on chronic renal dialysis because such use may lead to the development of hypermagnesemia. Excessive intake of Zinc may lead to overdosage symptoms like nausea, severe vomiting, dehydration, restlessness and sideroblastic anaemia (secondary to Zinc induced copper depletion).

DRUG INTERACTIONS: - It can interact due to concomitant use of magnesium containing antacids and calcitriol, digitalis, barbiturates or anticonvulsants, corticosteroids, Cholestyramine, Ketoconazole, verapamil and other calcium channel blockers, Oestrogens, fluoroquinolones, phenytoin, tetracyclines, thiazides and phosphate binding agents.

ADVERSE REACTIONS: Early-Weakness, headache, somnolence, nausea, vomiting, dry mouth, constipation, muscle pain, bone pain,anorexia, abdominal pain or stomach ache and metallic taste and metallic taste. Late - 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, nephrocalcinosis, dystrophy, sensory disturbances, dehydration, apathy, arrested growth, urinary tract infections, and rarely, overt psychosis.

Marketed by:

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(Additional information is available on request)