

GEMITROL KIT

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

Abbreviated Prescribing information for GEMITROL KIT (Combipack of Calcitriol, Calcium Carbonate & Zinc Capsules and Risedronate Sodium Tablet U.S.P.)

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

PHARMACOLOGICAL PROPERTIES:

Mechanism of action: Calcitriol: In physiological amounts it augments the intestinal absorption of calcium and phosphate and plays a significant part in the regulation of bone mineralisation. The defective production of calcitriol in chronic renal failure contributes to the abnormalities of mineral metabolism found in that disorder. **Risedronate sodium:** At the cellular level, Risedronate inhibits osteoclasts. The osteoclasts adhere normally to the bone surface, but show evidence of reduced active resorption (for example, lack of ruffled border). **Calcium carbonate:** Calcium suppresses PTH secretion and decreases bone turnover. Increased levels of PTH are known to contribute to age-related bone loss, especially at cortical sites, while increased bone turnover is an independent risk factor of fractures. **Zinc Sulfate:** Adequate zinc is required for normal growth and tissue repair. Urinary elimination of zinc is increased in osteoporotic women. Zinc depletion is shown to diminish the response of oral calcitriol when administered orally. Supplementary zinc not only improves calcitriol response but also helps to arrest bone loss in old postmenopausal women.

DOSAGE AND ADMINISTRATION: As directed by physician. To be taken orally with water and Do not take two tablets on any day.

CONTRAINDICATION: In all diseases associated with hypercalcaemia, in patients with evidence of metastatic calcification, in patients with known hypersensitivity to mentioned ingredients and (or drugs of the same class) and any of the constituent excipients. Angioedema, generalized rash, bullous skin reactions, Stevens-Johnson syndrome and toxic epidermal necrolysis have been reported, If there is evidence of vitamin D toxicity, Abnormalities of the esophagus which delay esophageal emptying such as stricture or achalasia, Inability to stand or sit upright for at least 30 minutes.

WARNINGS & PRECAUTIONS: There is a close correlation between treatment with calcitriol and the development of hypercalcaemia. All other vitamin D compounds and their derivatives, should be withheld during treatment with Calcitriol, An abrupt increase in calcium intake because of changes in diet. Patients and their families should be advised that strict adherence to the prescribed diet is mandatory and they should be instructed on how to recognise the symptoms of hypercalcaemia. Calcitriol increases inorganic phosphate levels in serum. If the patient is switched from a long acting vitamin D preparation increasing the risk of hypercalcaemia. Calcitriol capsules contain sorbitol. Patients with rare hereditary problems of fructose intolerance should not take Calcitriol capsules.

DRUG INTERACTION: Dietary instructions, especially concerning calcium supplements, should be strictly observed, and uncontrolled intake of additional calcium-containing preparations avoided, A relationship of functional antagonism exists between vitamin D analogues, which promote calcium absorption, and corticosteroids, which inhibit it, Magnesium-containing drugs (e.g. antacids) may cause hypermagnesaemia and should therefore not be taken during therapy with Calcitriol by patients on chronic renal dialysis. Other medication includes Calcium Supplements/Antacids, Hormone Replacement Therapy,

Aspirin/Nonsteroidal Anti-Inflammatory Drugs, H2 Blockers and Proton Pump Inhibitors (PPIs).

ADVERSE REACTIONS: Hypersensitivity, Urticaria, Hypercalcaemia, Decreased appetite, Polydipsia, Dehydration, Weight decreased, Apathy, Psychiatric disturbances, Headache, Muscular weakness, Sensory disturbance, Somnolence, Cardiac arrhythmias, Abdominal pain, Nausea, Vomiting, Constipation, Abdominal pain upper, Paralytic ileus, Rash, Erythema, Pruritus, Growth retardation, Urinary tract infection, Polyuria, Nocturia, Calcinosis, Pyrexia, Thirst, Blood creatinine increased

Manufactured by:

TORRENT PHARMACEUTICALS LTD.

Indrad-382 721, Dist. Mehsana, INDIA

At:Plot No. 708/6,

Behind Somnath Temple, Somnath Road,

Dabhel Village, Nani Daman-396 215

IN/GEMITRIL KIT- 35 mg and 0.25 mcg+200 mg+7.5 mg /JULY -21/02/ABPI

(Additional information is available on request)