DICALTROL

Capsule

DRUG INTERNATIONAL LTD.

Composition : Each dicaltrol soft gelatin capsule contains calcitriol BP 0.25mcg.

Indications : **Predialysis patients : Dicaltrol** is indicated in the management of secondary hyperparathyroidism and resultant metabolic bone disease in patients with moderate to severe chronic renal failure not yet on dialysis. In children, the creatinine clearance value must be corrected for a surface area of 1.73 square meters.

Dialysis patients : Dicaltrol is indicated in the management of hypocalcaemia and the resultant metabolic bone disease in patients undergoing chronic renal dialysis. In these patients, **Dicaltrol** administration enhances calcium absorption, reduces serum alkaline phosphatase levels and may reduce elevated parathyroid hormone levels and the histological manifestations of osteitis fibrosa cystica and defective mineralization.

Hypoparathyroidism patients : Dicaltrol is also indicated in the management of hypocalcaemia and its clinical manifestations in patients with post surgical hypoparathyroidism, idiopathic hypoparathyroidism and pseudohypoparathyroidism.

Osteoporosis : Dicaltrol is also indicated for the treatment of established postmenopausal osteoporosis and senile osteoporosis.

Dosage & administration : Predialysis Patients : The recommended initial dosage of Dicaltrol is 0.25 mcg/day in adults and pediatric patients 3 years of age and older. This dosage may be increased if necessary to 0.5 mcg/day.

Dialysis Patients : The recommended initial dose of **Dicaltrol** is 0.25 mcg/day. If a satisfactory response in the biochemical parameters and clinical manifestations of the disease state is not observed, dosage may be increased by 0.25 mcg/day at 4 to 8-week intervals. During this titration period, serum calcium levels should be obtained at least twice weekly, and if hypercalcaemia is noted, the drug should be immediately discontinued until normocalcaemia ensues. Patients with normal or only slightly reduced serum calcium levels may respond to **Dicaltrol** doses of 0.25 mcg every other day. Most patients undergoing hemodialysis respond to doses between 0.5 and 1mcg/day.

Hypoparathyroidism : The recommended initial dosage of **Dicaltrol** is 0.25 mcg/day given in the morning. If a satisfactory response in the biochemical parameters and clinical manifestations of the disease is not observed, the dose may be increased at 2 to 4 week intervals. During the dosage titration period, serum calcium levels should be obtained at least twice weekly and if hypercalcaemia is noted, **Dicaltrol** should be immediately discontinued until normocalceamia ensues. Careful consideration should also be given to lowering the dietary calcium intake. Most adult patients and pediatric patients age 6 years and older have responded to dosages in the range of 0.5 mcg to 2 mcg daily.

Pediatric patients in the 1 to 5 year age group with hypoparathyroidism have usually been given 0.25mcg to 0.75mcg daily. The number of treated patients with pseudohypoparathyroidism less than 6 years of age is too small to make dosage recommendations.

Postmenopausal Osteoporosis : The recommended dose for **Dicaltrol** is 0.25 mcg twice daily. Serum calcium and creatinine levels should be determined at 4 weeks, 3 and 6 months and at 6 monthly intervals there after.

Contraindications : Dicaltrol should not be given to patients with hypercalcaemia or evidence of metastatic calcification. The use of **Dicaltrol** in patients with known hypersensitivity to calcitriol and any of the constituent excipients is contraindicated.

Precautions : All other vitamin D compounds and their derivatives, including proprietary compounds or food stuffs which may be fortified with vitamin D, should be withheld during treatment with **Dicaltrol**. Since **Dicaltrol** effects phosphate transport in the gut and bone, the dose of phosphate-binding agent may need to be modified. **Dicaltrol** should be given cautiously to patients on digitalis, because hypercalcaemia in such patients may precipitate cardiac arrhythmias. **Dicaltrol** therapy should always be started at the lowest possible dose and should not be increased without careful monitoring of the serum calcium.

Side effects : Hypercalcaemia and hypercalciuria are the major side effects of **Dicaltrol**. The clinical features of hypercalcaemia include anorexia, nausea, vomiting, headache, weakness, apathy and somnolence. More severe manifestations may include thirst, dehydration, polyuria, nocturia, abdominal pain, paralytic ileus and cardiac arrhythmias.

Use in pregnancy and lactation : Dicaltrol should be given only when the potential benefit has been weighed against the possible hazard to the fetus. Mothers should not breast-feed while taking **Dicaltrol.**

Drug Interactions : Cholestyramine has been reported to reduce intestinal absorption of fat soluble vitamins; as such it may impair intestinal absorption of **Dicaltrol**. Some reports have shown that the concomitant administration of thiazide with **Dicaltrol** causes hypercalcaemia. Ketoconazole may inhibit both synthetic and catabolic enzymes of **Dicaltrol.**

Storage : Store below 30°C in a dry place.

Packing : Each box contains 60's capsule in blister pack.