Improcal®

Calcitriol

Description
Calcitriol (**Improcal®**) is a synthetic vitamin D analog which is active in the regulation of the absorption of calcium from the gastrointestinal tract and its utilization in the body.

Mode of action
Calcitriol (**Improcal®**) increases the uptake of calcium in the blood by (1) increasing the uptake of calcium from the gut into the blood, (2) decreasing the transfer of calcium from blood to the urine by the kidney, (3) preventing overall loss of calcium from bone.

Pharmacokinetics
Absorption: Rapidly absorbed from the intestine. Peak serum concentrations (above basal values) were reached within 3 to 6 hours following oral administration of single doses of 0.25 to 1.0 mcg.
Distribution: Calcitriol is approximately 99.9% bound in blood. Calcitriol and other vitamin D metabolites are transported in blood by an alpha-globulin vitamin D binding protein.
Metabolism: In vivo and in vitro studies indicate the presence of two pathways of metabolism for calcitriol. The first pathway involves the 24-hydroxylase as the first step in catabolism of calcitriol. There is definite evidence of 24-hydroxylase activity in the kidney; this enzyme is also present in many target tissues which possess the vitamin D receptor such as the intestine. The end product of this pathway is a side chain shortened metabolite, calcitroic acid. The second pathway involves the conversion of calcitriol via the stepwise hydroxylation of carbon-26 and carbon-23, and cyclization to yield ultimately 1á, 25R(OH)$_2$-26, 23S-lactone D$_3$.
Excretion: Enterohepatic recycling and biliary excretion of calcitriol occur. The metabolites of calcitriol are excreted primarily in feces.

Composition
Improcal® 0.25 mcg Capsule: Each capsule contains Calcitriol BP 0.25 mcg.

Indications
• Postmenopausal osteoporosis • Renal osteodystrophy in patients with chronic renal failure, particularly those undergoing hemodialysis • Post-surgical hypoparathyroidism • Idiopathic hypoparathyroidism • Pseudohypoparathyroidism • Vitamin D dependent rickets.

Dosage & administration
The optimal daily dose of Calcitriol (**Improcal®**) must be carefully determined for each patient on the basis of the serum calcium level. Calcitriol (**Improcal®**) can be administered orally either 0.25 mcg or 0.50 mcg.
A prerequisite for optimal efficacy of Calcitriol is adequate but not excessive calcium intake (in adults: approx. 800 mg daily) at the beginning of therapy.
Postmenopausal osteoporosis
The recommended dosage is 0.25 mcg twice daily or 0.50 mcg once daily. Serum creatinine levels should be determined at 4 weeks, 3 and 6 months and 6 monthly intervals thereafter.
Renal osteodystrophy (Dialysis patients)
The recommended initial dose of Calcitriol (**Improcal®**) is 0.25 mcg/day. Patients with normal or only slightly reduced serum calcium levels may respond to Calcitriol doses of 0.25 mcg every other day. Most patients undergoing hemodialysis respond to doses between 0.5 and 1 mcg/day.
Hypoparathyroidism & Rickets
The recommended initial dosage of Calcitriol (**Improcal®**) is 0.25 mcg/day given in the morning. If a satisfactory response is not observed, the dose may be increased at 2 to 4 week intervals.
Predialysis patients:
The recommended initial dosage of Calcitriol (**Improcal®**) 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.
Child dose: 1 month - 3 years of age, the recommended initial dosage of Calcitriol is 10 to 15 ng/kg/day.

Contraindications
Calcitriol should not be given to patients with hypercalcemia or evidence of vitamin D toxicity. Use of Calcitriol in patients with known hypersensitivity to Calcitriol (or drugs of the same class) or any of the inactive ingredients is contraindicated.

Side effects
Adverse events associated with Calcitriol therapy are similar to those encountered with excess vitamin D intake, i.e. hypercalcemia syndrome, or calcium intoxication.

Use in pregnancy and lactation
Pregnancy Category C. There is no evidence to suggest that Vitamin D is teratogenic in humans even at very high doses. Calcitriol should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
Calcitriol may be excreted in human milk. Mothers may breast feed while taking Calcitriol but serum calcium levels of the mother and infant should be monitored.

Precautions
Excessive dosage of Calcitriol induces hypercalcemia and in some instances hypercalciuria; therefore, early in treatment during dosage adjustment, serum calcium should be determined twice weekly.
In dialysis patients, a fall in serum alkaline phosphatase levels usually antedates the appearance of hypercalcemia and may be an indication of impending hypercalcemia. An abrupt increase in calcium intake as a result of changes in diet (e.g. increased consumption of dairy products) or uncontrolled intake of calcium preparations may trigger hypercalcemia.
Patients with normal renal function taking Calcitriol should avoid dehydration. Adequate fluid intake should be maintained.

Drug interactions
Uncontrolled intake of additional calcium containing preparations should be avoided. Concomitant treatment with a thiazide diuretic increases the risk of hypercalcemia. Calcitriol dosage must be determined with care in patients undergoing treatment with digitalis. Magnesium containing drugs (e.g. Antacids) may cause hypermagnesemia.

Over dosage
Administration of Calcitriol to patients in excess of their daily requirements can cause hypercalcemia, hypercalciuria, and hyperphosphatemia.
High intake of calcium and phosphate concomitant with Calcitriol may lead to similar abnormalities.

Storage: Store in a cool (Below 25˚ C temperature) and dry place protected from light.

Packaging
Improcal® 0.25 mcg Capsule: Each carton contains 10X5 Calcitriol BP capsules.

Opsonin Pharma
ideas for healthcare

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