Only for the use of Medical Professionals

Caloren®

Calcitriol

Description

Caloren® is a preparation of synthetic Calcitriol. Calcitriol is a crystalline compound, which occurs naturally in humans. It is soluble in organic solvents but relatively insoluble in water. It is the active form of vitamin D3 (cholecalciferol) which stimulates intestinal calcium transport. The known sites of action of Calcitriol are intestine, bone, kidney and parathyroid gland.

Indications

Caloren® is indicated in the management of severe renal impairment requiring vitamin D therapy and management of hypocalcemia in patients undergoing chronic renal dialysis. It has been shown to significantly reduce elevated parathyroid hormone levels. Reduction of PTH has been shown to result in an improvement in renal osteodystrophy.

Dosage and administration

The optimal dose of Caloren® injection must be carefully determined for each patient. The effectiveness of Caloren® injection therapy is predicated on the assumption that each patient is receiving an adequate and appropriate daily intake of calcium. The RDA for calcium in adults is 800 mg.

The recommended initial dose of Caloren® injection, depending on the severity of hypocalcemia and/or secondary hyperparathyroidism, is 1 mcg (0.02 mcg/kg) to 2 mcg administered 3 times weekly, approximately every other day. Doses range of as small as 0.5 mcg and as large as 4 mcg three times weekly have been used as an initial dose. If a satisfactory response is not observed, the dose may be increased by 0.5 to 1 mcg at two to four week intervals. During the titration period serum calcium, phosphorus and **parathyroid hormone (**PTH) levels should be obtained. The dosing must be individualized and commensurate with PTH serum calcium and phosphorus levels.
Following is the suggested approach in dose titration

PTH levels	Calcitriol Dose
The same or increasing	Increase
Decreasing by <30%	Increase
Decreasing by >30%, <60%	Maintain
Decreasing by >60%	Decrease
One and one-half to three times the upper limit of normal	Maintain

Use in pregnancy & lactation

There are no adequate and well-controlled studies in pregnant women. Calcitriol injection should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

It is not known whether this drug is excreted in human milk. A decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Precautions

Excessive dosage of Calcitriol injection induces hypercalcemia and in some instances hypercalciuria. Calcitriol injection should be given cautiously to patients on digitalis, because hypercalcemia in such patients may precipitate cardiac arrhythmias. Discontinuation of Calcitriol injection therapy may result in rebound effect, therefore, appropriate titration downward to a maintenance dose is recommended. If hypercalcemia develops, the drug should be discontinued immediately.

Side effects

The early side effects of Calcitriol injection are weakness, headache, somnolence, nausea, vomiting, dry mouth, constipation, muscle pain, bone pain and metallic taste. Late side effects are polyuria, polydipsia, anorexia, weight loss, nocturia, conjunctivitis (calcific), pancreatitis, photophobia, rhinorrhea, pruritus, hyperthermia, decreased libido, elevated BUN, albuminuria, hypercholesterolemia, elevated SGOT and SGPT, ectopic calcification, hypertension, cardiac arrhythmias and, rarely, overt psychosis. Occasional mild pain on injection has been observed.

Contraindications

Calcitriol Injection should not be given to patients with hypercalcemia or evidence of vitamin D toxicity.

Warnings

Since Calcitriol injection is the most potent metabolite of vitamin D available, vitamin D and its derivatives should be withheld during treatment. A non-aluminum phosphate-binding compound should be used to control serum phosphorus levels in patients undergoing dialysis. Chronic hypercalcemia can lead to generalized vascular calcification, nephrocalcinosis and other soft-tissue calcification.

Drug interactions

Magnesium-containing antacid and Calcitriol injection should not be used concomitantly, because such use may lead to the development of hypermagnesemia.

Over dose

Administration of Calcitriol injection to patients in excess of their requirements can cause hypercalcemia, hypercalciuria and hyperphosphatemia. General treatment of hypercalcemia (greater than 1 mg/dL) consists of immediate discontinuation of Calcitriol injection therapy, institution of a low calcium diet and withdrawal of calcium supplements.

Pharmaceutical precautions

Store in a cool, dry place at 15º-30ºC. Protect from light.

Presentation
Caloren® 1 mcg/ml IV injection: A sterile, isotonic, clear, and colorless to yellow, aqueous solution for intravenous injection. Caloren® is available in 1 ml ampoule. Each ml contains Calcitriol 1 mcg.

Package quantities
Caloren® 1mcg/ml IV injection: Carton of 1 ampoule (1ml) in a plastic tray

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