Calcitrol® Licap

Calcitriol BP

Composition

Each **Calcitrol® Licap** liquid filled hard gelatin capsule contains Calcitriol BP 0.25 mcg (biologically active form of vitamin D_3)

Pharmacology

Calcitriol is one of the most important active metabolites of vitamin D_3. It is normally formed in the kidneys from its precursor, 25-hydroxycholecalciferol. Calcitriol promotes intestinal absorption of calcium and regulates bone mineralization. The pharmacological effect of a single dose of Calcitriol lasts about 3-5 days. The key role of calcitriol is the regulation of calcium homeostasis, which includes stimulation effects on osteoblastic activity in the skeleton.

Indication

- Established postmenopausal osteoporosis
- Renal osteodystrophy in patients with chronic renal failure, particularly those undergoing haemodialysis
  Postsurgical hypoparathyroidism
- Idiopathic hypoparathyroidism
- Pseudohypoparathyroidism
- Vitamin D-dependent rickets
- Hypophosphataemic vitamin D resistant rickets

Dosage & administration

The optimal daily dose of **Calcitrol® Licap** must be carefully determined for each patient on the basis of the serum calcium level.

A prerequisite for optimal efficacy of **Calcitrol® Licap** is adequate but not excessive calcium intake (in adults: approximately 800 mg daily) at the beginning of therapy.

Postmenopausal osteoporosis

The recommended dosage for Calcitrol 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 thereafter.

Renal osteodystrophy (dialysis patients)

The initial daily dose is 0.25 mcg in patients with normal or only slightly reduced serum calcium levels, doses of 0.25 mcg every alternative day are sufficient.

Hypoparathyroidism and rickets

The recommended initial dose of Calcitrol is 0.25 mcg per day given in the morning. In patients with renal osteodystrophy or hypoparathyroidism and rickets if within 2-4 weeks satisfactory response is not observed by usual dose then dose may be increased at 2-4 weeks intervals.

Elderly patients

No specific dosage modifications are required in elderly patients.

Side effect

The incidence of adverse effects reported from clinical use of Calcitriol over a period of 15 years in all indications is very low. Occasional acute symptoms include anorexia, headache, vomiting and constipation. Chronic effects may include dystrophy, fever with thirst, polyuria, dehydration, apathy and urinary tract infection.

Contraindication

Calcitriol is contraindicated in patients with known hypersensitivity to any of its ingredients. Calcitriol is also contraindicated in all diseases associated with hypercalcemia.

Use in pregnancy & lactation

There is no evidence to suggest that vitamin D is teratogenic in humans even at very high doses. Calcitrol should be used during pregnancy only if the benefits outweigh the potential risk to the fetus.
Mothers may breast feed while taking Calcitrol but serum calcium levels of the mother and infant should be monitored.

Drug interaction

Uncontrolled intake of additional calcium containing preparations should be avoided. Concomitant treatment with a thiazide diuretc increases the risk of hypercalcemia. Calcitriol dosage must be determined with care in patients undergoing treatment with digitalis, as hypercalcemia in such patients may precipitate cardiac arrhythmias. Magnesium containing drugs (eg. antacids) may cause hypermagnesemia. The dosage of phosphate binding agents must be adjusted in accordance with the serum phosphate concentration.

Precaution

During Calcitrol therapy as soon as the serum calcium level rises to 1 mg/100 ml above normal or serum creatinine rise above 120 micromole/L the dosage of Calcitrol should be substantially reduced or treatment stopped altogether until normocalcemia ensues.

Storage

Store blow 25° C, protected from light and moisture. Keep out of the reach of the children.

How supplied

Calcitrol® Licap: Box containing 3 x 10 liquid filled hard gelatin capsules in Alu-PVDC blister pack.

Manufactured by

SQUARE
PHARMACEUTICALS LTD.
BANGLADESH