Encatrol

Calcitriol BP

Presentation

Encatrol capsule: Each soft gelatin capsule contains Calcitriol BP equivalent to Calcitriol 0.25 mcg.

Description

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

Indication

Calcitriol is indicated for the treatment of -

- Established postmenopausal osteoporosis
- Renal osteodystrophy in patients with chronic renal failure, particularly those undergoing haemodialysis
- Secondary hyperparathyroidism in patients with moderate to severe chronic renal failure (pre-dialysis)
- Postsurgical hypoparathyroidism
- Idiopathic hypoparathyroidism
- Pseudohypoparathyroidism
- Vitamin D-dependent rickets
- Hypophosphataemic vitamin D-resistant rickets
- Prevention of corticosteroid induced osteoporosis

Dosage & Administration

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

Patients	Type of disease	Dosage & Guidelines
Adult	Post-menopausal osteoporosis	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)	0.25 mcg daily. If no satisfactory response is observed within 2-4 weeks, the daily dosage may be increased by 0.25 mcg at 2-4 weeks interval.
	Secondary hyper-parathyroidism (pre-dialysis patients)	0.25 mcg daily.
	Hypoparathyroidism & Rickets	0.25 mcg daily in the morning. If no satisfactory response is observed by usual dose within 2-4 weeks then dose may be increased at two to four weeks interval.
	Prevention of corticosteroid induced osteoporosis	0.5-0.75 mcg per day. Serum calcium and creatinine levels should be obtained at two to four weeks after initiating treatment then at three and six months and every six months intervals thereafter.
Elder	No specific dosage modifications are required in elderly patients.	
Infants & Children	As for adults, the optimal daily dosage for children must be determined on the basis of the serum calcium level.	

Contraindication

Calcitriol is contraindicated in all diseases associated with hypercalcemia, metastatic calcification and patients with known hypersensitivity to Calcitriol or drugs of the same class.

Side Effect

The most commonly reported adverse reaction is hypercalcaemia. The incidence of side 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 has occurred. Chronic effects may include dystrophy, fever with thirst, polyuria, dehydration, apathy and urinary tract infection.

Precaution

During Calcitriol therapy serum calcium level should be determines twice daily. If the serum calcium level increased above normal level (normal level is 9-11 mg/100 ml) or serum creatinine rises above 120 micromole/L the dosage of Calcitriol should be reduced or stopped immediately until normocalcemia ensures.

Use in Pregnancy & Lactation

Pregnancy: The drug should be used during pregnancy only if the benefits outweigh the potential risk to the fetus.

Lactation: It should be assumed that exogenous Calcitriol passes into the breast milk. In view of the potential for hypercalcaemia in the mother and for adverse reactions from Calcitriol in nursing infants, mothers may breastfeed while taking Calcitriol, provided that the serum calcium levels of the mother and infant are monitored.

Drug Interaction

Uncontrolled intake of additional calcium containing preparation should be avoided. Concomitant treatment with a thiazide diuretic increases the risk of hypercalcemia. The dosage of Calcitriol must be determined with care in patients undergoing treatment with digitalis, as hypercalcemia in such patients may precipitate cardiac arrhythmias. Magnesium containing drugs (e.g. antacids) may cause hypermagnesemia. The dose of phosphate binding agents must be adjusted in accordance with the serum phosphate concentration (normal values: 2-5 mg/100 ml).

Overdose

Administration of Calcitriol to patients in excess of their daily requirements can cause hypercalcemia, hypercalciuria and hyperphosphatemia.

Commercial Packaging

Box containing 3 x 10 soft gelatin capsules in blister strips.

Manufactured by:

Globe Pharmaceuticals Ltd.

Noakhali, Bangladesh.