

# Ostriol

Calcitriol  
0.25 mcg Capsule

Calcitriol is one of the most important active metabolites of vitamin D<sub>3</sub>. It is normally formed in the kidneys from its precursor, 25-hydroxycholecalciferol. Calcitriol promotes intestinal absorption of calcium and regulates bone mineralization. The key role of Calcitriol is the regulation of calcium homeostasis, which includes stimulation effects on osteoblastic activity in the skeleton.

## COMPOSITION

Each liquid filled hard HPMC capsule contains Calcitriol BP 0.25 mcg.

## INDICATION

- Post-menopausal osteoporosis
- Renal osteodystrophy
- Postsurgical hypoparathyroidism
- Idiopathic hypoparathyroidism
- Pseudohypoparathyroidism
- Secondary hyperparathyroidism in patients with moderate to severe chronic renal failure (pre-dialysis)
- Vitamin D dependent rickets

## DOSAGE AND ADMINISTRATION

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

### *In Post-menopausal Osteoporosis*

The recommended dose of Calcitriol is 0.25 mcg twice daily.

### *In Renal Osteodystrophy (dialysis patients)*

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

### *In Hypoparathyroidism and Rickets*

The recommended initial dosage of Calcitriol is 0.25 mcg/day which given in the morning. If within 2-4 weeks satisfactory response is not observed by usual dose then dose may be increased at 2-4 weeks intervals.

### *Secondary hyperparathyroidism in patients with moderate to severe chronic renal failure (pre-dialysis)*

The recommended initial dosage of Calcitriol is 0.25 mcg/day in adults and pediatric patients 3 years of age or older. This dosage may be increased if necessary to 0.5 mcg/day. For pediatric patients less than 3 years of age, the recommended initial dosage of Calcitriol is 10 to 15 ng/kg/day.

### *In Elderly*

No dosage adjustment are required.

## CONTRAINDICATION

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

## SIDE EFFECT

Occasional symptoms include anorexia, headache, vomiting and constipation. Chronic effects may include dystrophy, fever, polyuria, dehydration, apathy and urinary tract infection.

## PRECAUTION

During Calcitriol therapy if the serum calcium levels rise to 1 mg/100 ml above normal or serum creatinine rises to >120 µmol/l, the dosage of Calcitriol should be substantially reduced or treatment stopped.

## DRUG INTERACTION

Concomitant treatment with a thiazide diuretics 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 (e.g., antacids) may cause hypermagnesemia.

## USE IN PREGNANCY AND LACTATION

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

## STORAGE CONDITION

Keep in a dry place away from light and heat. Keep out of the reach of children.

## HOW SUPPLIED

Each box contains 30 liquid filled hard HPMC capsules in Alu-Alu blister pack.

Manufactured by:

**NIPRO JMI Pharma Ltd.**  
Comilla, Bangladesh.