

## **PP Alfa-DOL 1.00 mcg Capsule**

### **COMPOSITION:**

PP Alfa-DOL 1.00 mcg Capsule: Each vegetable capsule contains Alfacalcidol 1.00mcg.

### **PRODUCT DESCRIPTION:**

PP Alfa-DOL 1.00 mcg Capsule - Two pieces, brick red, size '0' hard vegetable capsules with clear banding containing yellowish to brownish oil liquid.

### **PHARMACOLOGY:**

Alfacalcidol is the metabolite of vitamin D and it acts as a regulator of calcium and phosphate metabolism. In the body, alfacalcidol is converted to calcitriol (1, 25- dihydroxyvitamin D3). The maintenance of normal calcium and phosphate concentrations is achieved by facilitation of intestinal calcium and phosphate absorption and reabsorption of calcium in the distal renal tubule.

### **PHARMACOKINETICS:**

Alfacalcidol is well absorbed from the gastrointestinal tract. Alfacalcidol itself is inactive and must undergo 25-hydroxylation to 1, 25-dihydroxyvitamin D3 (Calcitriol) in the liver to elicit metabolites effects.

The reported elimination half-life of alfacalcidol in serum is approximately 3 hours in normal subjects. Alfacalcidol is excreted mainly in the bile and faeces with only small amount appearing in urine.

### **INDICATION:**

Disease caused by disturbances in the calcium metabolism as a consequence of reduced endogenous production of 1,25-dihydroxyvitamin D3.

Renal osteodystrophy, postoperative or idiopathic hypoparathyroidism, pseudohypoparathyroidism, as adjunct to the management of tertiary hyperparathyroidism, vitamin D-resistant rickets or osteomalacia, vitamin D-dependent rickets, neonatal hypocalcaemia or rickets, malabsorptive of calcium, osteoporosis, malabsorptive and nutritional rickets, and osteomalacia.

### **RECOMMENDED DOSE:**

#### **Adults:**

Usual starting dose is 1 mcg/day.

The dose maybe adjusted by increments of 0.25-0.5mcg. Plasma levels should be measured at weekly intervals initially. When the dose is stabilized, the measurements may be taken every 2-4 weeks. Most people respond to doses between 1 – 3 mcg/day.

When there is biochemical or radiographic evidence of bone healing, the dose may be decreased. The general maintenance dose is 0.25 – 1mcg / day.

**Elderly:**

The usual starting dose is 0.5mcg /day.

**Children between 5 to 20kg:**

The usual starting dose is 0.05mcg/kg body weight /day.

**Children 20kg and above:**

The usual starting dose is 1mcg/day.

**ROUTE OF ADMINISTRATION:**

Oral

**CONTRAINDICATIONS:**

Contraindicated when there is a biochemical evidence of hypercalcaemia.

Known hypersensitivity to alfacalcidol, vitamin D or any of its analogues and derivatives.

**WARNING AND PRECAUTION:**

During treatment with PP Alfa-DOL 1.00 mcg Capsule, serum calcium and serum phosphate should be monitored regularly especially in children, patients with renal impairment and patients receiving high doses. PP Alfa-DOL 1.00 mcg Capsule should be used with caution for patients being treated with cardioactive glycosides or digitalis.

**INTERACTIONS WITH OTHER MEDICATIONS:**

- There is an increased risk of hypercalcaemia if vitamin D is given with thiazide diuretics, calcium, or phosphate. Plasma- calcium concentrations should be monitored in such situation.
- Some antiepileptics may increase vitamin D requirements (e.g. carbamazepine, phenobarbital, phenytoin, and primidone.)
- Rifampicin and isoniazid may reduce the effectiveness of vitamin D.
- Corticosteroids may counteract the effect of vitamin D.

**PREGNANCY AND LACTATION:**

If you are pregnant or breastfeeding, PP Alfa-DOL 1.00 mcg Capsule should only be used if considered essential by the physician.

**SIDE EFFECTS:**

Excessive intake of alfacalcidol may lead to the development of hypercalcaemia.

**OVERDOSE AND TREATMENT:**

Hypercalcaemia can be rapidly corrected by stopping treatment until plasma calcium levels return to normal. Severe hypercalcaemia may require intervention with loop diuretics, IV fluids and corticosteroids.

**STORAGE CONDITION:**

Store in a dry place below 30°C.

**PACK SIZE:****PP Alfa-DOL 1.00 mcg Capsule**

Bottle of 10, 30, 50, 60 and 90 capsules.

**MANUFACTURED BY:**

**PAHANG PHARMACY SDN. BHD.** (10826-K)

Lot 5979, Jalan Teratai, 5 1/2 Miles Off, Jalan Meru, 41050  
Klang, Selangor Darul Ehsan.

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