OSTEO-ALFA®

Alfacalcidol **ألفا –أوستيو**

ألفاكالسيدول

Description:
OSTEO-ALFA® (Alfacalcidol) is a 1α-hydroxy-vitamin D3 which is rapidly converted in the liver to 1.25-dihydroxy-vitamin D3, the metabolite of vitamin D which acts as a regulator of Calcium and phosphate homeostasis.
Impaired endogenous production of 1.25-dihydroxy-vitamin D3 by the kidneys contributes to the disturbances in mineral metabolism found in several disorders, including renal bone disease, hypoparathyroidism, and vitamin D-dependent rickets.
These disorders require high doses of vitamin D for their correction but only small doses of OSTEO-ALFA®.
As compared with Vitamin D, the main advantage of OSTEO-ALFA® is the more rapid onset and reversal of action which allows a more accurate dose titration and decreases the risk of prolonged hypercalcaemia
Properties:
OSTEO-ALFA® is well absorbed from gastrointestinal tract; and mainly excreted in the bile and faeces.
Indications:
OSTEO-ALFA® is indicated in:
Diseases caused by disturbances in the Calcium metabolism in consequence of reduced endogenous production of 1.25-dihydroxy-vitamin D3.
Renal osteodystrophy, postoperative or idiopathic hypoparathyroidism, pseudo-hypoparathyroidism, as an adjunct to the management of tertiary hyperparathyroidism, vitamin D-resistant rickets or osteomalacia, vitamin D-dependent rickets, neonatal hypocalcaemia or rickets, malabsorption of Calcium, osteoporosis, malabsorptive and nutritional rickets, and osteomalacia.
Dosage and administration:
Initial dose:
Adults and children above 20 kg weight: 1.0 µg daily.
Children under 20 kg body weight: 0.05 µg/kg/day.
Patient notes:
- Most patients will respond to doses between 1 and 3 µg daily and the maintenance doses are generally in the range of 0.25 - 2 µg daily.
- It is important to adjust the dosage according to the biochemical responses to avoid hypercalcaemia. Indices of response include levels of serum Calcium, alkaline phosphatase, parathyroid hormone, urinary Calcium excretion as well as radiographic and histological investigations. Patients with marked bone disease (other than those with renal failure) may tolerate higher doses without developing hypercalcaemia. However, failure of the serum Calcium to rise promptly in osteomalacic patients does not necessarily mean that a higher dose is required, since Calcium from increased intestinal Calcium absorption may be incorporated into demineralized bone.
- The dose requirements generally decrease in patients with bone disease when there is biochemical or radiographic evidence of bone healing and in hypoparathyroid patients after normal serum Calcium levels have been obtained.
Contraindications:
Hypersensetivity to Vitamin D or its derivatives.
Precautions:
- Throughout the treatment with Alfacalcidol, regular serum Calcium determinations are essential. Indeed, Alfacalcidol should be used only when adequate facilities are available for monitoring the serum Calciumlevel and other appropriate biochemical parameters on a regular basis.
Frequency of monitoring: Plasma Calcium levels should be measured at weekly to monthly intervals depending on the progress of the patient. Frequent estimations are necessary in the early stages of treatment (particularly when the plasma Calcium is already relatively high) and later when there is evidence of bone healing. Plasma Calcium levels should also be estimated regularly during the initial treatment of disorders without significant bones involvement, e.g. hypoparathyroidism. If hypercalcaemia occurs, Alfacalcidol should be stopped immediately until serum Calcium levels return to normal (in about one week) and then resumed at half the previous dose. The risk of hypercalcaemia depends on factors such as the degree of any mineralization defect, renal function, and the dose of Alfacalcidol. Hypercalcaemia will occur if the dose of Alfacalcidol is not reduced appropriately when there is biochemical evidence of bone healing (e.g. return towards normal in the level of plasma alkaline phosphatase). Prolonged hypercalcaemia should be avoided, particularly in chronic renal failure.
- In patients with renal bone disease, Alfacalcidol should be given in combination with a phosphate-binding agent to prevent hyperphosphataemia which is known to increase the risk of metastatic calcification.
Use during pregnancy and lactation:
Alfacalcidol should only be used in pregnancy and during lactation if considered essential by the physician.
Drug interactions:
Patients currently taking barbiturates or other anticonvulsants may need larger doses of Alfacalcidol to produce the desired effect.
Side effects:
Apart from hypercalcaemia, no other side-effects have been reported.
Overdosage:
Hypercalcaemia is treated by stopping treatment with Alfacalcidol. Severe hypercalcaemia may require additional treatment with a “loop” diuretic, intravenous fluids and corticosteroids.
Storage conditions:
Store up to 30ºC.
Presentation:
OSTEO-ALFA® 0.25: Each Soft gelatin capsule contains Alfacalcidol 0.25 µg in packs of 30 and 100 softgels.
OSTEO-ALFA® 1.0: Each Soft gelatin capsule contains Alfacalcidol 1.0 µg in packs of 30 and 100 softgels.
Excipients:-
- OSTEO-ALFA® 0.25µg: Ethanol, Vitamin E, Arachis Oil, Gelatin, Glycerin, Methylparaben, Propylparaben, Red Iron Oxide, Titanium Dioxide & Purified Water.
- OSTEO-ALFA® 1µg: Ethanol, Vitamin E, Arachis Oil, Gelatin, Glycerin, Methylparaben, PropylpaPropylparaben, Red Iron Oxide, Black Iron Oxide, Titanium Dioxide & Purified Water.