D3-HIGH NANO SHOTS

For the use of a Registered Medical Practitioner or Hospital or a Laboratory only

Abbreviated Prescribing information for D3-HIGH NANO SHOTS [Cholecalciferol (Vitamin D3) Oral Solution 60,000 IU]

[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: Cholecalciferol, also called as vitamin D3, is produced naturally by ultraviolet irradiation of the provitamin, 7-dehydrocholesterol (a precursor of vitamin D) in the skin. Absorbed cholecalciferol requires metabolic activation. The circulating vitamin undergoes hydroxylation in the liver with the help of the enzyme, vitamin D 25-hydroxylase to form 25-hydroxycholecalciferol (calcidiol), which is the predominant circulating metabolite. Further hydroxylation in the kidneys (in response to need for phosphorus and calcium) forms 1,25-dihydroxycholecalciferol (calcitriol) with the help of 1alpha-hydroxylase. Calcidiol possesses some intrinsic activity, but calcitriol is the most active vitamin D metabolite with respect to initiating intestinal transport of calcium and phosphate and mobilizing calcium from bone. Calcitriol may prevent phosphaturia by inhibiting parathyroid hormone secretion. Conversion to calcitriol is stimulated by the parathyroid hormone, as well as decreases in serum inorganic phosphate levels. Reduced renal conversion of calcidiol to calcitriol contributes to altered calcium haemostasis and osteodystrophy in uraemia.

INDICATION: It is indicated for the treatment of Vitamin D3 deficiency

DOSAGE AND ADMINISTRATION: Adults: Vitamin D 3 60000 IU to be given once a week for a period of 8 weeks, followed by maintenance daily dose as directed by the physician. Oral It can be dispensed onto a spoon and taken as is or to facilitate the intake it can also be mixed with a small amount of cold or lukewarm food immediately prior to use. The patient should be sure to take the entire dose.

CONTRAINDICATION: Hypercalcaemia., Malabsorption syndrome, Hypervitaminosis D, Renal osteodystrophy with hyperphosphatemia (risk of metastatic calcification; however, vitamin D therapy can begin once serum phosphate levels have stabilized)

WARNINGS & PRECAUTIONS: In patients with severe renal impairment, vitamin D in the form of cholecalciferol is not metabolized normally and another form of vitamin D should be used. Conditions like arteriosclerosis or cardiac function impairment may be exacerbated due to the possibility of hypercalcaemia and elevated serum cholesterol concentrations Cholecalciferol should be administered with caution in patients with hyperlipidaemia as it could potentially exacerbate Low-density lipoprotein LDL elevation. Administration of cholecalciferol in patients with hyperphosphatemia may put the patient at risk of metastatic calcification; normalization of phosphate levels indicated prior to therapy. Liver disease may, in turn, impair the absorption of cholecalciferol.

DRUG INTERACTIONS: The co-administration of phenytoin or phenobarbital or barbiturates will not affect plasma concentrations of vitamin D but may reduce endogenous plasma levels of calcitriol by accelerating metabolism. Since blood level of calcitriol will be reduced, higher doses of cholecalciferol may be necessary if these drugs are administered simultaneously.

ADVERSE REACTIONS: Rash, itching/swelling, severe dizziness, trouble in breathing, nausea, vomiting, constipation, loss of appetite, increased thrist, increased urination, mental/mood changes, unusual tiredness, anorexia, weight loss, polyuria, heart arrhythmias, kidney stones, nephrocalcinosis, renal failure, hypertension, psychosis, nocturia, polydipsia, hypercalciuria, reversible azotaemia, worsening GI symptoms, anemia, mild acidosis.

MARKETED BY

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