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

Abridged Prescribing Information

DePURA by Sanofi™
Vitamin D3 Oral Solution 60000 IU

THERAPEUTIC CATEGORY:
Vitamins

COMPOSITION:
Each 5ml syrup contains:
Cholecalciferol I.P. 60000 IU in a flavoured sugar free base
Excipients …… q.s.
Colour: Tartrazine supra
Appropriate overages of vitamin added

THERAPEUTIC INDICATION:
Treatment and prevention of vitamin D deficiency states

DOSAGE AND ADMINISTRATION
Adults: Vitamin D3 60000 IU to be given once a week for a period of 8 weeks, followed by maintenance daily dose as directed by the physician.

SAFETY-RELATED INFORMATION
Contraindications: Hypersensitivity to cholecalciferol, ergocalciferol or Vitamin D metabolites (eg. calcitriol, calcifediol, alfacalcidol, calcipotriol), Hypercalcemia or hypercalciuria, Diseases and/or conditions, which lead to hypercalcaemia (e.g. nephrocalcinosis, myeloma, bone metastases, primary hyperparathyroidism, sarcoidosis, prolonged immobilisation accompanied by hypercalcaemia), Nephrolithiasis, and Hypervitaminosis D

Precautions & Warnings: The product should be prescribed with caution to patients suffering from sarcoidosis, impairment of renal function, suffering from cardiac conditions like arteriosclerosis, in elderly patients on concomitant treatment with cardiac glycosides or diuretics and patients with a high tendency to calculus formation. In case of hypercalciuria or signs of impaired renal function the dose should be reduced, or the treatment discontinued. The content of this product should be considered when prescribing other medicinal products containing vitamin D and preparation containing calcium. In patients with compromised calcium metabolism serum concentrations of phosphate should be checked during the vitamin D therapy to reduce the risk of ectopic calcification. Medical supervision is recommended for use of this product in children.

Pregnancy & Lactation: The product is not recommended during pregnancy in patients without a vitamin D deficiency. Vitamin D3 passes into breast milk hence should be considered while giving additional vitamin D to the child.

Adverse Reactions: High dose of cholecalciferol can cause weakness, fatigue, sleepiness, headache, loss of appetite, dry mouth, metallic taste, nausea and vomiting. Vitamin D toxicity, including nephrocalcinosis/ renal failure, hypertension can occur with prolonged use of cholecalciferol, relatively low doses can produce toxicity in hypersensitive infants and children. Hypervitaminosis D is reversible upon discontinuation of treatment unless renal damage is severe.

For full prescribing information please write to: Sanofi India Ltd., Sanofi House, CT Survey No. 117-B, L&T Business Park, Saki Vihar Road, Powai, Mumbai – 400 072

Updated: May 2023
Source: DePURA by Sanofi™ PI