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

Abridged Prescribing Information

Vitamin D3 Oral Solution 400 IU

DePURA KIDS by Sanofi NANO DROPS

COMPOSITION
Each 0.5ml contains: Cholecalciferol I.P. 400 IU (In nano droplet form)

THERAPEUTIC INDICATION: Prevention of vitamin D3 deficiency

DOSAGE
0-1 year of age: 400 IU/day
1-18 years of age: 600IU/day
or as directed by physician only.

SAFETY-RELATED INFORMATION
Contraindications: Hypersensitivity to cholecalciferol, ergocalciferol or Vitamin D metabolites; 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, , hypervitaminosis D

Precautions & Warnings: The product should be prescribed with caution to patients suffering from sarcoidosis due to risk of increased metabolism of vitamin D into its active form. During long-term treatment, serum calcium levels should be followed and renal function should be monitored through measurements of serum creatinine. In case of hypercalciuria or signs of impaired renal function the dose should be reduced or the treatment discontinued. The product should be used with caution in patients with impairment of renal function and the effect on calcium and phosphate levels should be monitored. In patients with severe renal insufficiency, vitamin D in the form of cholecalciferol is not metabolised normally and other forms of vitamin D should be used. Caution is required in patients suffering from cardiac conditions like arteriosclerosis due to the possible exacerbation related to hypercalcaemia and in patients with hyperlipidemia due to possibility of LDL elevation. 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.

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.

For full prescribing information, please contact: Sanofi India Ltd., Sanofi House, CT Survey No 117-B, L&T Business Park, Saki Vihar Road, Powai, Mumbai 400072

Created : October 2015
Updated: Apr 2020

Source : Depura by Sanofi Kids PI