sanofi

In Vitamin D deficiency

DePURA

by Sanofi™

Vitamin D3 Oral Solution 60,000 IU

Designed to deliver more

Vitamin D3 Oral Solution 60000 IU

DePURA by Sanofi™

For therapeutic use

Composition

Each 5ml contains:

Cholecalciferol I.P.	60000 IU
(In Nano Droplet form)	
In a flavoured sugar free base	
Excipients	q.s.

Colour: Tartrazine Supra

Appropriate overages of vitamin added.

Indications

Treatment and prevention of vitamin D deficiency states

Dosage

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.

Pediatric use

As prescribed by the Physician only.

Use in special population

Pregnancy:

The product should be used during pregnancy only in case of a vitamin D deficiency. It is not recommended during pregnancy in patients without a vitamin D deficiency.

Studies in animals have shown reproductive toxicity of high doses of vitamin D. There are no indications that vitamin D at therapeutic doses is teratogenic in humans. Overdose of vitamin D has been associated with teratogenic effect in animals.

Lactation:

Vitamin D can be used during breast feeding. Vitamin D3 passes into breast milk. This should be considered while giving additional vitamin D to the child.

Hepatic Insufficiency:

The intestinal absorption of cholecalciferol may be markedly impaired; conversion to calcifediol may also be reduced significantly, with the requirement of high doses. Agents not requiring hepatic hydroxylation (eg. calcitriol, alphacalcidol) are preferred.

Renal Insufficiency:

Although only small amounts of a vitamin D dose are recovered in the urine, metabolic conversion to calcitriol is impaired and higher doses are generally required in most conditions. Agents not requiring hepatic hydroxylation (eg. Calcitriol, alphacalcidol) are preferred.

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
- Hypervitaminosis D

Precautions and 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. These patients should be monitored with regard to the calcium content in serum and urine. During long-term treatment, serum calcium levels should be followed and renal function should be monitored through measurements of serum creatinine.

Monitoring is especially important in elderly patients on concomitant treatment with cardiac glycosides or diuretics and in 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 product should be used with caution in patients with impairment of renal function and the effect on calcium and phosphate levels should be monitored. The risk of soft tissue calcification should be taken into account.

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. The content of vitamin D should be considered when prescribing other medicinal products containing vitamin D. Additional doses of vitamin D should be taken under close medical supervision. In such cases it is necessary to monitor serum calcium levels and urinary calcium excretion frequently.

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. Prescription of this product with other vitamin D supplements should be done under close medical supervision. In such cases serum calcium levels should be monitored.

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.

Drug Interactions

Thiazide diuretics reduce the urinary excretion of calcium. Due to the increased risk of hypercalcaemia, serum calcium should be regularly monitored during concomitant use of thiazide diuretics.

Concomitant use of phenytoin or barbiturates may reduce the effect of vitamin D since the metabolism increases.

Concomitant use of Vitamin D with Vitamin D analogues, is not recommended due to the additive effect and increased toxic potential.

Excessive dosing of vitamin D can induce hypercalcaemia, which may increase the risk of digitalis toxicity and serious arrhythimias due to the additive inotropic effects. The electrocardiogram (ECG) and serum calcium levels of patients should be closely monitored.

Glucocorticoid steroids may increase vitamin D metabolism and elimination.

Systemic corticosteroids reduce calcium absorption. Moreover, the effect of vitamin D may be decreased.

Simultaneous treatment with ion exchange resins such as cholestyramine or laxatives such as paraffin oil may reduce the gastrointestinal absorption of vitamin D. Therefore, a time interval as long as possible between the intakes is recommended.

The absorption and therefore the efficacy of ketoconazole will be decreased by the concomitant intake of this product.

Concomitant treatment with rifampicin can decrease the effect of vitamin D3 because of metabolic activation.

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. Metabolism and nutrition disorder like Hypercalcaemia and hypercalciuria is uncommon. Skin and subcutaneous disorders like pruritus, rash and urticaria are rarely observed.

Overdosage

Treatment of hypercalcaemia: The treatment with vitamin D must be discontinued. Treatment with thiazide diuretics, lithium, vitamin A, and cardiac glycosides must also be discontinued. Rehydration, and, according to severity, isolated or combined treatment with loop diuretics, bisphosphonates, calcitonin and corticosteroids should be considered. Serum electrolytes, renal function and diuresis must be monitored. In severe cases, ECG and CVP should be followed.

In hypervitaminosis D cases of weakness, fatigue, muscle pain, polydipsia, polyuria, decreased appetite have been reported.
Overdose can lead to hypervitaminosis and hypercalcaemia.
Symptoms of hypercalcaemia may include anorexia, thirst, nausea, vomiting, diarrhea,constipation, abdominal pain, muscle weakness, anorexia, nocturia, headache,fatigue, mental disturbances, polydipsia, polyuria, bone pain, nephrocalcinosis, renal calculi and in severe cases, cardiac arrhythmias. Extreme hypercalcaemia may result in coma and death. Persistently high calcium levels may lead to irreversible renal damage and soft tissue calcification.

Functional properties of this technology are unique. Not to be substituted#

Storage

Store below 25°C. Protect from direct sunlight.

Presentation

Vitamin D3 60000 IU/5ml in a 5 ml bottle.

Manufactured by:

Pulse Pharmaceuticals Pvt. Ltd.,
At: Khata No. 845/713 and 1108/970/1, 34th K. M., Tumakuru Road, T. Begur, Nelamangala, Bengaluru Rural - 562123.

Marketed by:

Sanofi Consumer Healthcare India Limited
3rd Floor, Sanofi House, CTS No.117-B, L&T Business Park,
Powai, Mumbai-400072, Maharashtra.

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