For consumer information only

EPIONE®-D3

(Vitamin D3 Chewable tablet)

Composition:

Each uncoated chewable tablet Contains:
Cholecalciferol IP..... 60000 I.U.
(As vitamin D3)
Excipients .....q.s.

Clinical Pharmacology:
Vitamin D is hydroxylated in the liver to form 25-hydroxycholecalciferol and then undergoes further hydroxylation in the kidney to form the active metabolite 1,25 dihydroxy cholecalciferol (calcitriol). In its biologically active form vitamin D3 stimulates intestinal calcium absorption, incorporation of calcium into the osteoid and release of calcium from bone tissue. In the small intestine it promotes rapid and delayed calcium uptake. The passive and active transport of phosphate is also stimulated. In the kidney, it inhibits the excretion of calcium and phosphate by promoting tubular resorption. The production of parathyroid hormone (PTH) in the parathyroid is inhibited directly by the biologically active form of vitamin D3. PTH secretion is inhibited additionally by the increased calcium uptake in the small intestine under the influence of biologically active vitamin D3.

Indications:
Prevention and treatment of vitamin D deficiency states. Hypocalcemic seizures, rickets, chronic illness.

Use in special population:

Pregnancy:
Maintenance doses of vitamins are generally considered safe during pregnancy. However fetal risk cannot be ruled out when administered in high doses in pregnancy.

Lactation:
Maintenance doses of vitamins are generally considered safe during lactation. However infant risk cannot be ruled out when administered in high doses during lactation.

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 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 renal hydroxylation (eg calcitriol) are preferred.

Contraindications:
Hypersensitivity to cholecalciferol, ergocalciferol, or vitamin D metabolites (eg calcitriol, calcifediol, alfacalcidol, calcipotriol). Hypercalcemia (exacerbation with enhanced toxicity) Hypervitaminosis D (worsening of condition, pretherapy 25-hydroxycholecalciferol levels should be considered in selected patients)

Precautions and Warnings:
Vitamin D should be used with caution in patients with impairment of renal function and the effects on calcium and phosphate levels should be monitored, the risk of soft tissue calcification should be taken into account. In patients with several 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. Vitamin D should be prescribed with caution to patients suffering from sarcoidosis because of the risk of increased metabolism of vitamin D to its active form. These patients should be monitored with regards to the calcium content in the serum and urine. Medical Supervision is required whilst on treatment to prevent hypercalcaemia.

Drug Interactions:
Calcipotriene is a drug that is similar to vitamin D. taking vitamin D along with calcipotriene might increase the effects and side effects of calcipotriene. Taking vitamin D along with digoxin might increase the effects of digoxin (Lanoxin) and lead to an irregular heartbeat.
Taking large amount of vitamin D along with diltiazem might decrease the effectiveness of diltiazem. When given along with antacids, vitamin D increases the absorption of aluminum salts.

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

Overdosage:
Although no long-term studies have examined higher doses of vitamin D on serum calcium levels, there are no reported cases of vitamin D intoxication to suggest that intakes of up to 4000 IU/d of vitamin D cause hypercalcemia. In healthy adults, 5 months of ingesting 10,000 IU/d of vitamin D neither caused hypercalcemia nor increased urinary calcium excretion, which is the most sensitive indicator for potential vitamin intoxication.

In case of toxicity immediate cessation of vitamin D intake is indicated, with a low-calcium diet, glucocorticoid administration, and fluid support. Vitamin D intoxication is usually reversible with these measures; gradual falls in serum calcium and mobilization of calcium from soft tissue occur. Recovery of renal function is seen unless renal damage was severe prior to treatment.

For therapeutic use.

Route of administration: Oral.

Type of tablet: Chewable tablet.

Flavour: Delicious Pineapple flavor.

Dosage: Each Vitamin D3 Tablet given once a week for a period of 8 to 12 week, or as directed by physician.

Storage:
Store in cool, dry and dark place.

Presentation: Epione D3 chewable tablet available as 1x 4 tablet strip.

Marketed By:

EPIONE®
Soothing Touch of Life...
(An ISO 9001:2015 Certified Co.)
www.epionepharma.com

EPIONE PHARMACEUTICALS PVT.LTD.

804, Suyog Center, Gultekdi, Pune-411037 (MH), India.