SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

VITOC-D DROPS 15ML

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:
Colecalciferol BP…….800 IU

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral drops

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Prevention and treatment of vitamin D deficiency
- Treatment of rickets
- As an adjunct to a specific therapy for osteoporosis in patients at risk of vitamin D deficiency

4.2 Posology and method of administration

Posology
Dosage & direction for use:

Dosage: Infants and children 0.5ml (400IU) once per day or as directed by doctor.

METHOD OF ADMINISTRATION
Administration of Children
In children, Vitoc D can be mixed with a small amount of children's foods, yogurt, milk, cheese or other dairy products. The parents should be warned not to mix Vitoc D into a bottle milk or container of soft food in case the child does not consume the whole portion, and dose not receive the full dose the parent should ensure that their child takes the entire dose. For children who are not breast-feeding, the prescribed dose should be administrate with a meal.

4.3 Contraindications

-Hypersensitivity to the active substance or to any of the excipients listed in section 6.1
-Medical conditions resulting in hypercalcaemia or hypercalciuria (patients with impaired renal calcium and phosphate elimination, treatment with benzothiadiazine derivates and immobilised patients)
-Calcium-containing nephroliths
-Hypervitaminosis D

-Severe arteriosclerosis
-Severe renal impairment

4.4 Special warnings and precautions for use

The extent of the vitamin D deficiency can be determined by measuring 25OHD (= 25-hydroxyvitamin D). In adults a 25OHD serum level of 80 ng/ml should not be exceeded. Values above 150 ng/ml constitute a health-threatening overdose.

During long-term treatment with Sapvit-D3, calcium levels in serum and urine should be regularly monitored. If necessary, the dose has to be adjusted according to serum calcium levels.

In case of hypercalcaemia or signs of impaired renal function the dose should be reduced or the treatment discontinued.

Renal function should be monitored during long-term treatment with Sapvit-D3 by measuring serum creatinine. Sapvit-D3 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 case of severe renal insufficiency, cholecalciferol is not utilized. When indicated, other vitamin D preparations should be used.

Cholecalciferol should be prescribed with caution to patients suffering from sarcoidosis (risk of increased metabolism of vitamin D into its active form) and patients with osteoporosis due to immobilisation (increased risk of hypercalcaemia).

It should be used with caution in patients on concomitant treatment with cardiac glycosides or thiazide diuretics (see section 4.5).

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.

Paediatric population

Especially in infants, concomitant use of other vitamin D-containing products should be avoided. If in doubt, the physician decides about additional use of vitaminenriched foods or baby foods and vitamin-D-containing medicines.

4.5 Interaction with other medicinal products and other forms of interaction

Increased risk of hypercalcaemia if given with thiazide diuretics, calcium or phosphate. Antiepileptics (e.g. carbamazepine, phenobarbitone, phenytoin & primidone) may increase vitamin D requirements. Rifampicin & isoniazid may reduce efficacy of vitamin D. Corticosteroids may counteract the effect of vitamin D. Digoxin or any cardiac glycoside. Reduced absorption when taken with cholestyramine, colestipol, mineral oil, orlistat. Ketoconazole.

4.6 Fertility, pregnancy and lactation

•Category A: Controlled studies in women fail to demonstrate a risk to the foetus in the 1st trimester (and there is no evidence of a risk in later trimesters), and the possibility of foetal harm remains remote.
If dose > US RDA.
•Category D: There is positive evidence of human foetal risk, but the benefits from use in pregnant women may be acceptable despite the risk (e.g., if the drug is needed in a life-threatening situation or for a serious disease for which safer drugs cannot be used or are ineffective).

4.7 Effects on ability to drive and use machines

Sapvit-D3 has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Cholecalciferol can cause the following undesirable effects, especially in overdose:

Adverse reactions frequencies are not known (cannot be estimated from the available data).

Metabolism and nutrition disorders:
Hypercalcaemia, hypercaluria.

Gastrointestinal disorders:
Constipation, flatulence, nausea, stomachache, diarrhoea.

4.9 Overdose

Overdose can lead to hypervitaminosis and hypercalcaemia. Hypervitaminosis is expressed in uncharacteristic symptoms such as headache, loss of appetite, weakness, weight loss, gastrointestinal disturbances (nausea, vomiting, constipation) and growth disorders.
Persisting hypercalcaemia may lead to polyuria, polydipsia, nausea, vomiting, constipation, muscle weakness, paresis, adynamia, nocturia, proteinuria, anorexia, hypercholesterolaemia, elevated transaminase levels, cardiac arryhthmias, hypertension and radiographically detectable soft tissue calcification.

The vitamin D effect is reversed in severe overdose. Bones are decalcified and calcium levels in blood and urine increase. Calcification can occur in tissue, blood vessels and kidneys. Furthermore, mental changes up to psychosis can occur.

Treatment
Treatment with vitamin D must be discontinued immediately and dehydration corrected in case of an intoxication. Other measures: diet low in calcium, calcitonin, glucocorticoids.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: vitamins; vitamin D and analogues; ATC code: A11CC05

Mechanism of action
Vitamin D regulates the calcium- and phosphate balance.
Cholecalciferol and to an even greater extent its hydroxylation products induce the formation of a calcium transport protein in the mucous membrane of the small intestine. This leads to increased absorption of calcium and phosphate from the intestine. In the kidneys vitamin D stimulates the reabsorption of calcium and phosphate.
A vitamin D deficiency leads to rickets in the growing organism and osteomalacia in adults.

The so called vitamin D_3 is regarded as a precursor of a steroid hormone according to its production, physiological regulation and mechanism of action. In addition to the physiological production in the skin, cholecalciferol can be supplied with food or as a medicinal product. As the physiological product inhibition of the cutaneous vitamin D synthesis is bypassed in the latter way, overdose and intoxications are possible.

5.2 Pharmacokinetic properties

Absorption
Vitamin D is easily absorbed from the gastrointestinal tract in the presence of bile. In case of reduced fat absorption, the absorption of vitamin D is also reduced.

Distribution
Vitamin D can be stored in adipose- and muscle tissue for a long time. The effect of cholecalciferol starts slowly and is longlasting.

Biotransformation
The active form of vitamin D_3 is 1,25-dihydroxycholecalciferol, which is formed by hydroxylation of cholecalciferol in liver and kidneys.

Elimination
Vitamin D and its metabolites are excreted mainly in the bile and faeces. Small amounts appear in the urine.

5.3 Preclinical safety data

Vitamin D has been shown to be teratogenic in high doses in animals. Many offspring of pregnant rabbits that have been treated with large doses of vitamin D have lesions anatomically similar to those of supravalvular aortic stenosis. In addition offspring with no aortic narrowing show vasculotoxicity similar to that of adults following acute vitamin D toxicity.
Cholecalciferol has no potential mutagenic or carcinogenic activity.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose
Tween 20
Sorbitol

Glycerin
Sodium benzoate
Colour
Tartrazine Supra
Mango Alphanso flavour 51315
Citric acid
(Monohydrate)
Purified water

6.2 Incompatibilities
Not applicable.
6.3 Shelf life
Shelf life: 2 years.

6.4 Special precautions for storage
Store in a dry place below 30° C. Protect from light.
6.5 Nature and contents of container
Box of one 15 ml amber glass bottle with Dropper and Pack Insert

6.6 Special precautions for disposal
NIL

7 MARKETING AUTHORISATION HOLDER AND MANUFACTURING SITE ADDRESS
Manufacturer:
Cachet Pharmaceuticals Pvt
Village And Post Thana,Baddi
Tehsil-Nalagarh,Solan District,
Himachal Pradesh 173 205 ,India

Marketing Authorisation Holder:
Cachet Pharmaceuticals Pvt. Ltd
415, Shah Nahar, Worli, Mumbai-400018
India

8 MARKETING AUTHORISATION NUMBER(S)

H2022/CTD8661/17756
9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

01/12/2022
10 DATE OF REVISION OF THE TEXT

01/12/2022