SUMMARY OF PRODUCT CHARACTERISTICS

1. **Name of the medicinal product:**

   VITOC-D SACHET

   (Colecalciferol Granules 60000 IU)

2. Qualitative and quantitative composition:

Each sachet of 1 gm contains:

Colecalciferol BP ……60,000 IU

Excipients…….q.s.

3. Pharmaceutical form: Powder for Oral Use.

4. Clinical particulars:

4.1 Therapeutic indications:

The prevention and treatment of vitamin D deficiency.

As an adjunct to specific therapy for osteoporosis in patients with vitamin D deficiency or at risk of vitamin D insufficiency.

Vitoc-D is indicated in adults, the elderly and adolescents.

4.2 Posology and method of administration:

Vitamin D deficiency in adults and the elderly (serum levels <25 nmol/l (<10 ng/ml)) 1/4 - 1 Sachet daily for up to 12 weeks dependent upon the severity of the disease and the patient's response to treatment.

Vitamin D insufficiency in adults and the elderly (serum levels 25 – 50 nmol/l (10-20 ng/mL)) and long-term maintenance therapy following treatment of deficiency in adults and the elderly and Prevention of vitamin D deficiency: 1/2-1 Sachet daily Vitamin D deficiency or insufficiency in children over 12 years – 1/2 Sachet daily depending on the severity of the disease and the patient's response to treatment. Should only be given under medical supervision.

As an adjunct to specific therapy for osteoporosis 1/2 Sachet daily

Vitoc-D should not be used in children under 12 years

4.3 Contraindications

Sensitivity to the ingredients listed.

4.4 Special warnings and precautions for use

Vitamin D 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 Colecalciferol is not metabolised normally and other forms of vitamin D should be used.

Caution is required in patients receiving treatment for cardiovascular disease.

Vitoc-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 regard to the calcium content in serum and urine.

Allowances should be made for vitamin D supplements from other sources. The need for additional calcium supplementation should be considered for individual patients. Calcium supplements should be given under close medical supervision.Medical supervision is required whilst on treatment to prevent hypercalcaemia.

This medicine contains arachis oil (peanut oil). If you are allergic to peanut or soya, do not use this medicinal product.

Vitoc-D should not be given to children.

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 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

Not Known

4.8 Undesirable effects

Adverse reactions are listed below, by system organ class and frequency. Frequencies are defined as uncommon (>1/1,000, <1/100) or rare (>1/10,000, <1/1,000).

Metabolism and nutrition disorders

Uncommon: Hypercalcaemia and hypercalciuria.

Skin and subcutaneous disorders

Rare: Pruritus, rash and urticaria.

4.9 Overdose

The most serious consequence of acute or chronic overdose would be hypercalciuria and hypercalcaemia due to vitamin D toxicity. Symptoms include nausea, vomiting, thirst, polydipsia, polyuria and constipation. Chronic overdoses can lead to vascular and organ calcifications as a result of hypercalcaemia. Treatment would consist of stopping all intake of calcium and vitamin D and rehydration.

5. Pharmacological properties

5.1 Pharmacodynamics properties

Colecalciferol (vitamin D3) is a steroid hormone that has long been known for its important role in regulating body levels of calcium and phosphorus, in mineralization of bone, and for the assimilation of Vitamin A. The classical manifestations of vitamin D deficiency is rickets, which is seen in children and results in bony deformaties including bowed long bones. Deficiency in adults leads to the disease osteomalacia. Both rickets and osteomalacia reflect impaired mineralization of newly synthesized bone matrix, and usually result from a combination of inadequate exposure to sunlight and decreased dietary intake of vitamin D. Common causes of vitamin D deficiency include genetic defects in the vitamin D receptor, severe liver or kidney disease, and insufficient exposure to sunlight. Vitamin D plays an important role in maintaining calcium balance and in the regulation of parathyroid hormone (PTH). It promotes renal reabsorption of calcium, increases intestinal absorption of calcium and phosphorus, and increases calcium and phosphorus mobilization from bone to plasma.

5.2 Pharmacokinetic properties

The first step involved in the activation of vitamin D3 is a 25-hydroxylation which is catalysed by the 25-hydroxylase in the liver and then by other enzymes. The mitochondrial sterol 27-hydroxylase catalyses the first reaction in the oxidation of the side chain of sterol intermediates. The active form of vitamin D3 (calcitriol) binds to intracellular receptors that then function as transcription factors to modulate gene expression. Like the receptors for other steroid hormones and thyroid hormones, the vitamin D receptor has hormone-binding and DNA-binding domains. The vitamin D receptor forms a complex with another intracellular receptor, the retinoid-X receptor, and that heterodimer is what binds to DNA. In most cases studied, the effect is to activate transcription, but situations are also known in which vitamin D suppresses transcription. Calcitriol increases the serum calcium concentrations by: increasing GI absorption of phosphorus and calcium, increasing osteoclastic resorption, and increasing distal renal tubular reabsorption of calcium. Calcitriol appears to promote intestinal absorption of calcium through binding to the vitamin D

receptor in the mucosal cytoplasm of the intestine. Subsequently, calcium is absorbed through formation of a calcium-binding protein.

Preclinical safety data

There are no pre-clinical data of relevance.

6. Pharmaceutical particulars

6.1 List of excipients: Lactose Anhydrous DC, Mannitol DC, Sucralose, Flavour Vanilla, Flavour Mixed Fruit Trusil 1038, Aerosil-200, Magnesium Stearate.

6.2 Incompatibilities

Not Applicable

6.3 Shelf life

24 months

6.4 Special precautions for storage

Store in a cool & dry place. Protect from light.

Keep out of reach of Children.

6.5 Nature and contents of container

1g Sachet × 10’s

6.6 Special precautions for disposal and other handling

Not Applicable

7. Name and Address of Manufacturer

Cachet Pharmaceuticals Pvt.Ltd.

Village - Thana, baddi, distt.-Solan, Himachal Pradesh, India.

8. Marketing authorization holder

Cachet Pharmaceuticals Pvt. Ltd

415, Shah Nahar, Worli, Mumbai 400 018. India.

9. Marketing authorization number(s)

Not Applicable

10. Date of first authorization/renewal of the authorization

Not Applicable

11. Date of revision of the text: Not Applicable