Composition: Each ml Oral Solution Contains Cholecalciferol (Vitamin D3) USP 400 IU/ml.

Pharmacology: Cholecalciferol (Vitamin D3) helps for the absorption & reabsorption of Calcium & Phosphorus. Vitamin D3 is essential for normal bone growth & to maintain bone density. It also reduces the severity of bacterial infection, improves lung function, prevents the risk of cancer (breast, colorectal) & helps to maintain adequate insulin levels for type 2 diabetes patients.

Indications: It is indicated for the treatment & prevention of (Vitamin D3) deficiency. It is also indicated as an adjunct to specific therapy for osteoporosis in patients with vitamin D3 deficiency.

## **Dosage & administration:**

Infant: 400 IU Per day beginning soon after birth.

0 to 6 months: 0.50 ml twice a day 6 months & above: 1.00 ml twice a day [The American Academy of Pediatrics (AAP) recommended that infant has to get 400 IU OF Vitamin D3 per day beginning soon after birth, an amount that is not possible to get from breast milk alone.]

Treatment of deficiency: Children and adolescents: The dose should be adjusted dependent upon desirable serum levels of 25-hydroxy-cholecalciferol 25(OH) D, the severity of the disease and the patients response to treatment. The daily dose should not exceed 1000 IU (5 drops) per day for infants <1 year, 2000 IU per day for children 1-10 years and 4000 IU per day for adolescents>11-years.

For pregnant women: The recommended daily intake for pregnant women is 400 IU (2 drops) however, in women who are considered to be vitamin D3 deficient a higher dose may be required (up to 2000 IU/day-10 drops). Or, as directed by the registered physician.



**Contraindications**: It is contraindicated in patients with known hypersensitivity to vitamin D3, or any other components of this drug.

**Precautions:** It should be used with caution in patients with impaired renal function and the effect on calcium & phosphate levels should be monitored.

**Side effects:** The general side effects are hypercalcemia, hypercalciuria, skin rash, pruritus, urticaria, nausea and abdominal pain.

Use in pregnancy and lactation: Studies have shown safe use of doses up to 4000 IU during pregnancy. The recommended daily intake for pregnant women is 400 IU, however in women who are considered to be vitamin D3 deficient a higher dose may be required. During pregnancy women should follow the advice of their medical practitioner as their requirements may vary depending on the severity of their disease and their response to treatment. Vitamin D3 and its metabolites are excreted in breast milk. The dose should be monitored for pregnant and lactating women.

**Use in child :** See Dosage and administration.

**Drug Interactions:** It interferes with phenytoin, barbiturates, glucocorticoids, certain laxative (such as liquid paraffin), actinomycin and imidazole antifungal agents.

Overdose: There is no data available.

**Storage**: Store below 30° C in a dry place. **Packing**: 20ml bottle with a plastic dropper. For measurement use supplied dropper.