United Pharmaceuticals

HI DEE®

Oral Solution Drops

Vitamin D3 (Cholecalciferol)

Description:

HI DEE® (Vitamin D3 (Cholecalciferol)) which maintains a healthy Calcium and Phosphorus levels in the body for strong bones and increases muscle strength in older adults, and it also plays an active role in a healthy immune response.

Vitamin D3 (Cholecalciferol) is the optimal form of vitamin D. It is the form of vitamin D that the body manufactures when the skin is exposed to UV radiation from sunlight (but the ability to do so decreases as we age), and the form of most efficiency for the body's needs.

Properties:

After oral administration, Vitamin D3 is absorbed from the intestine and transported in the blood via protein binding to reach the liver where first hydroxylation occurs and then to the kidney where second hydroxylation occurs.

Vitamin D is stored in reserved compartments such as adipose and muscle tissues. Its plasma half-life is several days. Vitamin D and their metabolites are excreted mainly in the bile and in faeces with only small amounts appearing in the urine.

Indications:

HI DEE® is indicated in the:

-Prevention of Rickets and Vitamin D Deficiency.

-Treatment of Vitamin D deficiency and/or rickets.

Dosage and administration:

-Prevention of Rickets and Vitamin D Deficiency:

•Premature neonates: 400 to 800 international units orally once daily (1-2 Drops)

•Breastfed neonates and infants (fully or partially breastfed): 400 international units orally once daily beginning in the first few days of life (1 Drop)

-Treatment of Vitamin D deficiency and/or rickets:

• < 1 month: 1000 IU/day orally for 2-3 months (3 Drops)

• 1–12 months: 1000–5000 IU/day orally for 2-3 months (3 – 13 Drops)

• > 12 months: 5000 IU/day orally for 2-3 months (13 Drops)

Contraindications:

Hypersensitivity to the active ingredient or any of the excipients.

Precautions:

• A special precaution should be taken in:

- Patients with hypercalcaemia.
- Infants, who may have increased sensitivity to its effects.
- Patients with renal impairment or calculi, or heart disease, who might be at increased risk of organ damage if hypercalcaemia occurred.
- Plasma phosphate concentrations should be controlled during vitamin D therapy to reduce risk of ectopic calcification.
- It is advised that patients receiving pharmacological doses of vitamin D should have their plasma-calcium concentration monitored at regular intervals, especially initially or if symptoms suggest toxicity.
- Similar monitoring is recommended in infants if they are breast fed by mothers receiving pharmacological doses of vitamin D.

Pregnancy and lactation:

Pregnancy: Hypercalcaemia during pregnancy may produce congenital disorders in the offspring, and neonatal hypoparathyroidism. However, the risks to the fetus of untreated maternal hypoparathyroidism are considered greater than the risks of hypercalcaemia due to vitamin D therapy.

Lactation: Vitamin D is distributed into breast milk, and its concentration appears to correlate with vitamin D levels in the serum of exclusively breast-fed infants. It is considered the use of vitamin D to be usually compatible with breast feeding, although it is recommended that the infant be closely monitored for hypercalcaemia or clinical manifestations of vitamin D toxicity if the mother is receiving pharmacological doses of vitamin D.

Drug Interactions:

- There is an increased risk of hypercalcaemia if vitamin D is given with thiazide diuretics and calcium. Plasma-calcium concentrations should be monitored in such situations.
- Some antiepileptics may increase vitamin D requirements (e.g. Carbamazepine, Phenobarbital, phenytoin, and primidone). Rifampicin and isoniazid may reduce the effectiveness of vitamin D.
- Corticosteroids may counteract the effect of vitamin D.

Side Effects:

Excessive intake of vitamin D leads to the development of hyperphosphataemia or hypercalcaemia. Associated effects of hypercalcaemia include hypercalciuria, ectopic calcification, and renal and cardiovascular damage.

Overdosage:

Symptoms: Include anorexia, lassitude, nausea and vomiting, constipation or diarrhea, polyuria, nocturia, sweating, headache, thirst, somnolence and vertigo.

Interindividual tolerance to vitamin D varies considerably; infants and children are generally more susceptible to its toxic effects.

The vitamin should be withdrawn if toxicity occurs. It has been stated that vitamin D dietary supplementation may be detrimental in persons already receiving an adequate intake through diet and exposure to sunlight, since the difference between therapeutic and toxic concentrations is relatively small.

Storage conditions:

HI DEE® Oral Solution Drops:

Store in cold place 2 - 8°C.

Presentation:

HI DEE® Oral Solution Drops: Each 5 drops (about 0.17ml) of the oral solution contains 2000 IU equivalent to 50 µg Vitamin D3 (Cholecalciferol) filled in 10ml bottle.

Also different strengths of HI DEE® Capsules are available in market such as:

-HI DEE® 2000IU Capsules

-HI DEE® 5000IU Capsules

-HI DEE® 10000IU Capsules

-HI DEE® 50000IU Capsules

This is a medicament

· Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
· Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
· The doctor and the pharmacist are experts in medicine, its benefits and risks.
· Do not by yourself interrupt the period of treatment prescribed for you.
· Do not repeat the same prescription without consulting your doctor.
· Keep medicament out of the reach of children.

COUNCIL OF ARAB HEALTH MINISTERS
UNION OF ARAB PHARMACISTS

The United Pharmaceutical Manufacturing Co. Ltd.
P.O. Box 69 Amman 11591, Jordan

June, 2015
M3-14-0768