Dan-D™

(CHOLECALCIFEROL)

Soft Gel Capsule

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COMPOSITION:
Dan-D Soft Gel Capsule 50,000 IU:
Each soft gel capsule contains:
Vitamin D_3 (Cholecalciferol) ..... 50,000 IU.

Product Specs.: Manufacturer's Specs.

Dan-D Soft Gel Capsule 200,000 IU:
Each soft gel capsule contains:
Vitamin D_3 (Cholecalciferol) ..... 200,000 IU.

Product Specs.: Manufacturer's Specs.

DESCRIPTION:
Cholecalciferol (Vitamin D_3) is the active form of vitamin D. Vitamin D is essential for normal bone growth, development and to maintain bone density. Stimulates calcium and phosphate absorption from small intestine; stimulates phosphate resorption in renal tubules; stimulates secretion of calcium into blood from bone.

PHARMACOKINETICS:
Cholecalciferol (Vitamin D_3) is formed in the skin under influence of UV rays and metabolized in two hydroxylation steps; at first in the liver and then in the kidney tissue into the biological active metabolite 1,25-dihydroxy-cholecalciferol which is involved fundamentally in the regulation of the calcium and phosphate balance together with parathyroid hormone and calcitonin.
Vitamin D in alimentary doses is absorbed from the nutrition almost completely together with the lipids and bile acids. Vitamin D reaches with the help of a specific transport protein in the liver where it is metabolized by a microsomal hydroxylase to 25-hydroxy-cholecalciferol. The excretion of vitamin D and its metabolites is carried out through bile/fecal pathway.

INDICATIONS:
1. As dietary supplement for prevention of Vitamin D deficiency in adults and children.
2. Prevention of Vitamin D deficiency in high risk patients with malabsorption, certain chronic diseases, disorders of metabolism, drugs or other causes.
3. Treatment of vitamin D deficiency states like rickets, osteomalacia and osteoporosis.
In all cases calcium supplements must be provided along with Vitamin D supplementation.

DOSAGE AND ADMINISTRATION:
Dan-D is to be administered orally. Dietary and other sources of Vitamin D must also be considered. Calcium intake should be adequate. It is advised to have Serum Vitamin D_3 level checked prior to capsule intake.
Children:
Vitamin D Deficiency: 5,000-50,000 IU, once a week, for 8 weeks or 5,000 IU, once a day, for 8 weeks.
Maximum dose:
10,000 international units per day.
Hypoparathyroidism:
50,000-200,000 IU PO once daily with calcium supplements
Familial Hypophosphatemia:
10,000-60,000 IU PO once daily with phosphate supplements
Patients with malabsorption syndromes, and patients on medications affecting vitamin D metabolism, suggested a higher dose (two to three times higher; at least 5,000-10,000 IU/day) 100,000 IU PO every 3 to 6 months of vitamin D to treat vitamin D deficiency
Vitamin-D Resistant Rickets:
In children > 12 months of age:
12,000-500,000 IU PO once daily. Continue until healing is established.
Adults:
Osteoporosis: Prophylaxis & treatment 800-1,000 IU PO with calcium supplements.
Fracture prevention in high risk patients with osteoporosis:
100,000 IU PO every 4 months.
Hypoparathyroidism, 50,000 to 200,000 IU daily. Calcium supplementation is also required.
Familial Hypophosphatemia: 10,000-60,000 IU PO daily with phosphate supplements.
Vitamin D Deficiency: 5,000 IU PO daily or 50,000 IU once a month until a biochemical or radiographic response is achieved.
Prevention of Vitamin D Deficiency in elderly >65 years of age:
100,000 IU every 3 months.
In cases of malabsorption, long term treatment with antiepileptics, corticosteroids and other conditions that lead to Vitamin D deficiency:
100,000 IU PO every 3 to 6 months.
It is important to obtain calcium, phosphorus, and Alkaline Phosphatase levels before and 1 month after initiating therapy.

CONTRAINDICATIONS:
Dan-D may not be used in the following conditions:
- Hypersensitivity to Cholecalciferol or any of the ingredients of the drug.
- Hypercalcemia and/or hypercalciuria.

Dan -D should not be administered to patients:
- With a tendency towards the formation of kidney stones containing calcium.
- With pseudohypoparathyroidism.

CAUTIONS:
Dan-D should be administered only with caution:
- to patients with a disturbed renal calcium and phosphate excretion.
- to patients taking anticonvulsants.
- to immobilized patients, e.g. by cast, (risk of the hypercalcemia, hypercalciuria).
- to patients with sarcoidosis since the risk of transformation of vitamin D into its active metabolites is increased. The calcium levels in plasma and urine should be supervised at these patients.

During long term therapy the calcium levels in the serum and in the urine should be supervised, and the kidney function should be checked by measuring the serum creatinine every 3 to 6 months. This check is particularly important for older patients and for patients taking cardiac glycosides or diuretics. In the case of hypercalcemia or reduced kidney function the dosage must be reduced or the therapy discontinued. It is advisable to discontinue the therapy if the calcium level in the blood exceeds 105mg/ml or if calciuria is >4 mg/kg/day in adults or 4-6 mg/kg/day in children. If other vitamin D containing drugs are administered, the dosage of Cholecalciferol must be taken into account. Additional administration of vitamin D or calcium should be carried out only under medical monitoring. In such cases the calcium levels in the serum and urine must be supervised.

PREGNANCY & LACTATION:
There is no evidence to suggest that vitamin D is teratogenic in humans even at very high doses. Cholecalciferol should be used during pregnancy only if the benefits outweigh the potential risk to the fetus. It should be assumed that exogenous Cholecalciferol passes into the breast milk. In view of the potential for hypercalcaemia in the mother and for adverse reactions from Cholecalciferol in nursing infants, mothers may breastfeed while taking Cholecalciferol, provided that the serum calcium levels of the mother and infant are monitored.

DRUG INTERACTIONS:
Thiazide diuretics: Concomitant administration can lead to hypercalcemia by the reduction of the renal calcium excretion. The calcium levels in the plasma and in the urine should therefore be supervised during a long-term therapy.
Phenytoin or barbiturates: These drugs can impair the effect of Cholecalciferol.
Glucocorticoids: The simultaneous administration of glucocorticoids can reduce the effect of Cholecalciferol.
Digoxin: The toxicity of cardiac glycosides can be increased during the therapy with vitamin D because of increased calcium levels (risk for arrhythmias). Patients should be supervised with regard to ECG and calcium levels in the plasma and in the urine.
Antacids (Magnesium-containing): Hypermagnesemia may develop when these agents are used concurrently with vitamin D, particularly in patients with chronic renal failure.
Cholestyramine, Colestipol, Mineral Oil: Intestinal absorption of vitamin D may be impaired. Patients on cholestyramine or colestipol should be advised to allow as much time as possible between the ingestion of these drugs and vitamin D.

ADVERSE EFFECTS:
The side effects of vitamin D result as consequence of the hypercalcemia. Hypercalcemia can appear depending on dosage and duration of therapy with its acute symptoms (arrhythmias, nausea, vomiting, psychic symptoms, and impaired consciousnesses) and chronic symptoms (polyuria, polydipsia, weight loss, kidney stone formation, nephrocalcinosis, extraosseous calcifications).

OVERDOSAGE:
In case of over dosage signs & symptoms of hypercalcemia are seen. They may include nausea, vomiting, at first often diarrhea may also occur. Later on constipation, anorexia, weakness, headache, muscle and joint pains, muscle weakness as well as drowsiness, azotemia, polydipsia and polyuria may be seen. Typical biochemical results are hypercalcemia, hypercalciuria as well as increased serum levels of 25-dihydroxycalciferol.

TREATMENT OF OVERDOSAGE:
The first measure is to stop the administration of the vitamin D preparation; a normalization of the hypercalcemia because of vitamin D intoxication lasts for several weeks. Calcium poor or calcium free nutrition, plenty of hydration, forced diuresis by means of furosemide as well as the administration of glucocorticoids, calcitonin or dialysis may be used according to the extent of the hypercalcemia. A specific antidote does not exist.

PRECAUTIONS:
- Store below 30°C.
- Patients suffering from renal diseases should use under medical supervision.
- Keep out of the reach of children.

PRESENTATION:
Dan-D Soft Gel Capsule 50,000 IU : Pack of 1 x 5 capsules.
Dan-D Soft Gel Capsule 200,000 IU : Pack of 1 x 1 capsule.

احتیاط:
۳۰ درجہ سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔
گردوں کے مریض اپنے معالج کے زیرِ نگرانی استعمال کریں۔
بچوں کی پہنچ سے دور رکھیں۔

خوراک:
مستند معالج کی ہدایت کے مطابق۔ (تجویز کیا جاتا ہے کہ کیپسول لینے سے پیشتر خون میں وٹامن ڈی ۳ کی مقدار کا تعین کروالیں)۔

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SHMZ International
101 Sundar Industrial Estate, Lahore, Pakistan.

Distributed by:
Nexpharm Healthcare (Pvt.) Ltd.
65 Industrial Estate, Kot Lakhpat, Lahore, Pakistan.

FOR FURTHER INFORMATION PLEASE CONTACT:

CCL Consumer Healthcare
Manufactured for:
CCL Pharmaceuticals (Pvt.) Ltd.
62 Industrial Estate, Kot Lakhpat, Lahore, Pakistan.