FRONT

Dan-D®

5 mg
Ampoule
1 ml

(CHOLECALCIFEROL)

Oral / I.M. Ampoule

200,000 IU

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COMPOSITION:
Each ml contains:
Cholecalciferol (Vitamin D_3) USP ..... 5 mg.
(200,000 IU).

Product Specs.: CCL Pharmaceuticals

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. 1,25-dihydroxy-cholecalciferol 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. The vitamin D is synthesized in the skin under influence of UV light from 7-dehydrocholesterol. The vitamin D reaches with the help of a specific transport protein 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:
- Prevention of Vitamin D Deficiency due to malabsorption, drugs, certain chronic diseases, disorders of metabolism or other causes.
- Treatment of vitamin D deficiency states.

These include the following:
Rickets: In children
Osteomalacia: In adults
In all cases calcium supplements must be provided along with Vitamin D supplementation.

DOSAGE AND ADMINISTRATION:
Dan-D is available as solution for intramuscular injection. It may also be administered orally.
Prevention:
a. Infants:
i. Breast fed infants not receiving Vitamin D enriched milk: 200,000 IU (1 ampoule) every 6 months.
ii. Breast fed infants receiving Vitamin D enriched milk: 100,000 IU (1/2 ampoule) every 6 months.
b. Children 1-5 years of age: 200,000 IU (1 ampoule) every 6 months.
c. Adults: 100,000 IU (1/2 ampoule) as single dose repeated every 3 months.
d. Pregnancy: 100,000 IU (1/2 ampoule) at 6^{th}-7^{th} month of pregnancy.
e. Elderly: 100,000 IU (1/2 ampoule) every 3 months.
f. In cases of malabsorption, long term treatment with antiepileptics ,corticosteroids and other conditions that lead to Vitamin D deficiency: 100,000 IU (1/2 ampoule) every 3 to 6 months.
Treatment:
a. Calcium Deficient Rickets: For children > 12months of age: 200,000 IU (1 ampoule) once per month repeated every 3 months until healing is established.
b. Osteomalacia: Adults: 100,000 IU (1/2 ampoule) once a week for 6-12 months.
c. Vitamin D Deficiency:
i. ***Children > 12 months of age:*** 100,000 IU (1/2 ampoule) once a month for 3 months, followed by 400-1000 IU/day as maintenance;
ii. ***Adults:*** 200,000 IU (1 ampoule) once a month for 2-3 months, followed by 100,000 IU (½ ampoule) once a month as maintenance.
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

PRECAUTIONS:
- ***Dan-D should be administered only with caution to patients:***
- With a disturbed renal calcium and phosphate excretion,
- Patients taking anticonvulsants.
- Immobilized patients, e.g. by cast, (risk of the hypercalcemia, hypercalciuria).
- Suffering from sarcoidosis since the risk of transformation of vitamin D into its active metabolites is increased.

BACK

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 >4mg/kg/day in adults or 4-6mg/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 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 can impair the effect of Cholecalciferol. The simultaneous administration of glucocorticoids can reduce the effect of Cholecalciferol. 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.

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 overdosage 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:
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.

INSTRUCTIONS:
- Store below 25°C.
- Protect from heat, sunlight and moisture.
- Improper storage may deteriorate the product.
- Keep out of the reach of children.
- To be sold on the prescription of a registered medical practitioner only.

PRESENTATION:
Dan-D Injection : 1 ml ampoule.

ہدایات:

۲۵ درجہ سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔
گرمی، دھوپ اور نمی سے بچائیں۔
نامناسب سٹوریج مصنوعات کی خرابی کا باعث بن سکتی ہے۔
بچوں کی پہنچ سے دور رکھیں۔
صرف ڈاکٹر کے نسخہ پر فروخت کریں۔

FOR FURTHER INFORMATION PLEASE CONTACT:

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