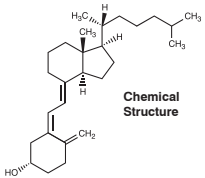
DFerol
(CHOLECALCIFEROL)

5mg/mL (200,000 IU)
Oral/I.M. Injection
Vitamin D_3

DESCRIPTION:
Cholecalciferol is the naturally occurring form of Vitamin D, also called Vitamin D_3. It is produced from 7- dehydrocholesterol, a sterol present in mammalian skin, by ultraviolet irradiation.
Calciferol is involved in bone fixation of calcium. It is indicated in prevention and treatment of Vitamin D deficiencies.


Chemical Structure

COMPOSITION:
Each ml contains:
Cholecalciferol (Vitamin D_3) B.P. 5mg

DOSAGE AND ADMINISTRATION:
Prevention: Infants receiving Vitamin enriched milk: ½ Ampoule (i.e. 100,000 IU) every 6 months.
Nursed infants or infants not receiving Vitamin D enriched milk or young children upto 5-years of age: 1 Ampoule (i.e. 200,000 IU) every 6-months:
Adolescents: 1 Ampoule (i.e. 200,000 IU) every 6-months during winter.
Pregnancy: ½ Ampoule (i.e. 100,000 IU) once during 6th or 7th month of pregnancy.
Elderly: ½ Ampoule (i.e. 100,000 IU) every 3-months. Digestive disorders, concomitant treatment with anti-epileptics, particular conditions not prescribed above ½ or 1 Ampoule every 3 or 6 months.
Vitamin D Deficiency: 1 Ampoule (i.e. 200,000 IU), which can be renewed once 1 to 6 months later.

WARNING & PRECAUTIONS:
This drug must not be used in the following cases: Hypersensitivity to any of the ingredients mainly to Vitamin-D. Hypercalcemia (abnormally high blood calcium levels). Hypercalciuria (excessive urinary elimination of calcium). Calcium lithiasis (kidney stones).

CONTRAINDICATIONS:
Vitamin D should not be given to patients with hypercalcemia or evidence of Vitamin-D toxicity, Use of Vitamin D in patients with known hypersensitivity to Vitamin D (or drugs of the same class) or any of the inactive ingredient is contraindicated.

PREGNANCY AND LACTATION:
This medicinal product can be prescribed during pregnancy or lactation if necessary. However it is preferable to consult your doctor before using this drug.

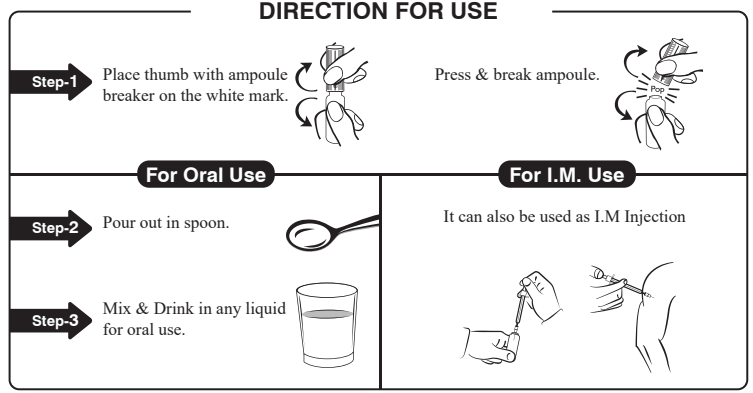
DRUG INTERACTIONS:
Cholestyramine: Cholestyramine has been reported to reduce intestinal absorption of fat soluble vitamins; as such it may impair intestinal absorption of any of Vitmain-D. **Thiazides:** Thiazides are known to induce hypercalcemia by the reduction of calcium excretion in urine. Some reports have shown that the concomitant administration of thiazides with Vitamin-D causes hypercalcemia, Therefore, precautions should be taken when co-administration is necessary. **Digitalis:** Vitamin D dosage must be determined with care in patients undergoing treatment with digitalis, as hypercalcemia in such patients may precipitate cardiac arrhythmias. **Ketoconazole:** Ketoconazole may inhibit both synthetic and catabolic enzymes of Vitamin D, Reductions in serum endogenous Vitamin D concentration have been observed following the administration of 300mg/day to 1200mg/day ketoconazole for a week to healthy men. **Corticosteroids:** A relationship of functional antagonism exists between Vitamin D analogues, which promote calcium absorption and corticosteroids, which inhibit calcium absorption. **Phosphate-Binding Agents:** Since Vitamin D also has effect on phosphate transport in the intestine, kidneys and bones, the dosage of phosphate binding agents must be adjusted in accordance with the serum phosphate concentration.

Vitamin D:
The co-administration of any of the Vitamin D analogues should be avoided as this could create possible additive effects and hypercalcemia.
Calcium Supplements: Uncontrolled intake of additional calcium-containing preparations should be avoided. Magnesium: Magnesium-containing preparations (e.g., antacids) may cause hypermagnesemia and should therefore not be taken during therapy with Vitamin D by patients on chronic renal dialysis.

OVERDOSAGE
In the event of an overdosage vitamin D_3, following symptoms may occur: headache, fatigue, slimming, growth retardation, nausea, vomiting, excess of urines, intense thirst, arterial hypertension. In case of any symptoms inform your doctor immediately.

UNDESIREABLE AND UNPLEASENT EFFECTS:
As with any medicine this product may produce unpleasant effects varying severity in some people. Consult your physician if any unwanted or unpleasant effect is observed.

DIRECTION FOR USE



INSTRUCTIONS:
Store below 30°C. Protect from heat & light. Avoid freezing and injection should not be used if container is leaking, solution is cloudy or it contains un-dissolved particles. To be sold on the prescription of a registered medical practitioner only.

PRESENTATION:
D Ferol Injections are available in 1mL x 5's ampoules with ampoule breaker, ampoule tray and leaf insert.

Manufactured for:
DANEEN PHARMA **Daneen Pharma (Pvt.) Ltd.**
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