



**DESCRIPTION:** Cholecalciferol is the naturally occurring form of Vitamin D, also called Vitamin D3. 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.

## COMPOSITION:

## **D4U** Injection:

Each ml contains:

Cholecalciferol (Vitamin D3) B.P. .....5mg

Genix Specs.

## DOSAGE AND ADMINISTRATION:

**Prevention:** Infants receiving Vitamin enriched milk: ½ Ampoule (i.e. 100,000 I.U.) 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 I.U.) every 6-months.

Adolescents: 1 Ampoule (i.e. 200,000 I.U.) every 6-months during winter.

**Pregnancy:** ½ Ampoule (i.e. 100,000 I.U.) from 6th or 7th month of pregnancy.

 $\textbf{Elderly:}\ \%\ \text{Ampoule (i.e. 100,000 I.U.) every 3-months. Digestive disorders, concomitant treatment with anti-epileptics, particular conditions$ 

not prescribed above:  $\frac{1}{2}$  or 1 Ampoule every 3 or 6 months.

Vitamin D Deficiency: 1 Ampoule (i.e. 200,000 I.U.), which can be renewed once 1 to 6 months later.

Alternate dosing: Infants less than 1 year: 8000 international units/week. Children older than 1 year: 800 international units/day.

Medium Dose Regimen: Patients less than 5 years: 12,000 international units/week for 12 weeks.

Patients 5 years or older: 50.000 international units/week for 12 weeks.

**High Dose Regimen:** Patient less than 5 years: 12.000 international units twice weekly for 12 weeks.

Patient 5 years or older: 50.000 international units twice weekly for 12 weeks.

**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.

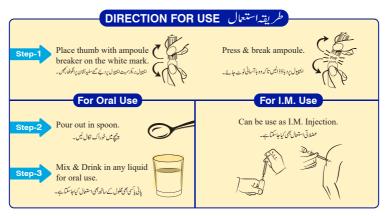
Pregnancy and Lactation: This medicinal product can be prescribed during pregnancy or lactation if necessary. However it is preferable to consult your doctor before using this drug.

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 D3, 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.

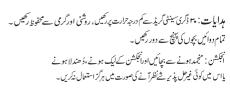
**UNDESIREABLE AND UNPLEASENT EFFECTS:** As with any medicine this product may produce unpleasant effects varying severity in some people. Consult your physician if any unwanted or unpleasant effect is observed.



INSTRUCTIONS: Store below 30°C. Protect from heat & light.

For Injection: Avoid freezing and injection should not be used if container is leaking, solution is cloudy or it contains un-dissolved particles.

PRESENTATION: D4U Injection are available in 1mlx5 ampoules with ampoule breaker.



Manufactured by:







