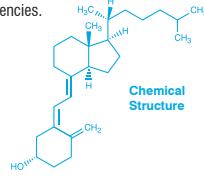


D4U™ 5mg/ml
Oral/I.M. Injection
Oral Drops 10ml
(CHOLECALCIFEROL) Vitamin D₃ analogue

ڈی فور یو
اورل ڈراپس اورل انجکشن
کولی کیلسی فیروول
(زیناٹی/ایسٹائی انجکشن)
5 ملی گرام/10 ملی لیٹر (۲۰۰۰۰۰ آئی پی)



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.

D4U Drops:
Each ml contains:
Cholecalciferol (Vitamin D₃) B.P.5mg

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.
Elderly: ½ Ampoule (i.e. 100,000 I.U.) 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 I.U.), which can be renewed once 1 to 6 months later.

PEDIATRIC DOSE OF DROPS:

Usual Pediatric Dose for Vitamin D Insufficiency:
Treatment of Vitamin D deficiency and/or rickets:
Infants 1 to 12 months: 1000 to 5000 International units/day for 2 to 3 months; once radiologic evidence of healing is observed, dose should be decreased to 400 international units/day.
Children older than 12 months: 5000 to 10,000 international units/day for 2 to 3 months; once radiologic evidence of healing is observed, dose should be decreased to 400 international units/day.
Prevention and treatment of Vitamin D Deficiency in cystic fibrosis:

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 Vitamin-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.

UNDESIRABLE AND UNPLEASANT 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 طریقہ استعمال

<p>Step-1</p> <p>Place thumb with ampoule breaker on the white mark.</p> <p>انجکشن پر دباؤ ڈالیں تاکہ وہ با آسانی ٹوٹ جائے۔</p>	<p>Press & break ampoule.</p> <p>انجکشن پر دباؤ ڈالیں تاکہ وہ با آسانی ٹوٹ جائے۔</p>
<p>For Oral Use</p> <p>Step-2</p> <p>Pour out in spoon.</p> <p>چمچے میں خوراک نکال لیں۔</p>	<p>For I.M. Use</p> <p>Can be use as I.M. Injection.</p> <p>عضلاتی استعمال بھی کیا جاسکتا ہے۔</p>
<p>Step-3</p> <p>Mix & Drink in any liquid for oral use.</p> <p>پانی یا کسی بھی مائع کے ساتھ بھی استعمال کیا جاسکتا ہے۔</p>	

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 1ml x 5 ampoules with ampoule breaker & leaflet.
D4U Oral Drops are available in 10ml amber green bottle & tamper evident dropper & leaflet.

Manufactured by:
GENIX Genix Pharma (Pvt.) Ltd.

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UAN: +92-21-111-10-10-11, Email: info@genixpharma.com

Manufactured by:
DANEEN Daneen Pharma (Pvt.) Ltd.

— PHARMA —
27-Sundar Industrial Estate, Sundar Raiwind Road Lahore, Pakistan.
Tel: +92-42-35297781-2, Email: info@daneenpharma.com

ہدایات: ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں، روشنی اور گرمی سے محفوظ رکھیں۔
تمام دوائیں بچوں کی پہنچ سے دور رکھیں۔

انجکشن: منجمد ہونے سے بچائیں اور انجکشن کے لیے کھولنے، دھندلا ہونے یا اس میں کوئی غیر حل پذیر شے نظر آنے کی صورت میں ہرگز استعمال نہ کریں۔



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