GEN-D
(CHOLECALCIFEROL)

5mg/ml
Oral/I.M. Injection
Oral Drops 10ml

Vitamin D_3 analogue

DESCRIPTION: Cholecalciferol is the naturally occurring form of Vitamin D. 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:
GEN-D Injection
Each ml contains:
Cholecalciferol (Vitamin D3) BP....5mg

GEN-D Oral Drops
Each ml (Approx. 30 drops) contains:
Cholecalciferol (Vitamin D3) BP....5mg
eq. to 200,000IU 1 drop contain 6666.66 IU
Cholecalciferol (Vitamin D3) BP
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. **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: 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 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.
DIRECTION FOR USE
For IM Use: Place thumb with ampoule breaker on the white mark Press & break ampoule.
For Oral Use: Pour out in spoon, Mix & Drink in any liquid.
INSTRUCTIONS: Store below 30°C. Protect from heat, light & moisture. Keep all medicines out of the reach of children.(For Injection: Avoid freezing and injection should not be used if container is leaking, solution is cloudy or it contains un-dissolved particles).
PRESENTATION: GEN-D Injection 1ml x 5 ampoules with ampoule braker, plastic tray & package insert. GEN-D Oral Drops 10ml with amber green bottle & tamper evident dropper with child lock cap & package insert.

For detailed information please contact:
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