



MEDLEY PHARMACEUTICALS

Medirol-D Injection

[Cholecalciferol (Vit.D₃)]

Composition: Each 1ml ampoule contains Cholecalciferol (Vit.D₃) 5mg or 200,000 I.U.

Description:

Medirol-D 1ml inj. is a clear, sterile oil based solution for intramuscular and oral use only. It contains Cholecalciferol or Vit.D₃ as an active ingredient which acts as an anti-ricketic agent.

Mechanism of action:

Calcitriol is the active form of Cholecalciferol achieved through enzymatic action in liver which increases the calcium level by increasing GI absorption of phosphorus and calcium, increasing osteoclastic reabsorption, and increasing distal renal tubular reabsorption of calcium. Calcitriol promote intestinal absorption of calcium through binding with vit.D receptor in the mucosal cytoplasm of the intestine. Subsequently calcium is absorbed through formation of a calcium-binding protein.

Indications:

Vitamin D₃ is used for the treatment of vitamin D deficiency or insufficiency refractory rickets, familial hypophosphatemia and hypoparathyroidism, and in the management of hypocalcaemia and renal osteodystrophy in patients with chronic renal failure undergoing dialysis. Also used in conjunction with calcium in the management and prevention of primary or corticosteroid-induced osteoporosis.

Biotransformation/ Drug Metabolism:

Cholecalciferol is hydroxylated in the liver by enzyme Vit.D 25-hydroxylase to form 25 -hydroxycholecalciferol (calcifediol). This further undergo hydroxylation in the kidney by the enzyme vit-D 1-hydroxylase to form the biologically active metabolite 1,25-dihydroxycholecalciferol(calcitriol). After its metabolism the metabolites are excreted mainly in the bile and faeces with only small amounts appearing in the urine. It may be distributed in the breast milk.

Contraindications:

hypercalcaemia; metastatic calcification

Cautions:

Take care to ensure correct dose in infants; monitor plasma calcium level in patients receiving high doses and in renal impairment.

Side effects:

Symptoms of over dosage include, nausea, anorexia, vomiting, lassitude, weight loss, polyurea, sweating, headache, thirst, vertigo and raised concentration of calcium and phosphate in plasma and urine.

Drug interactions:

Vit.D₃ requirements possibly increase when given with Barbiturates, Carbamazepines, primidone and phenytoin. Increased risk of hypercalcaemia when Medirol-D is taken with Thiazides and related diuretics.

Dosage and Administration:



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ISO 9001-2008 Certified Company
Medley Pharmaceuticals
41-A, P.S.I.E. Jhang Bahtar Road,
Wah Cantt- Rawalpindi



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For adults: oral: 400 I.U is required for prevention of simple Vit.D deficiency/day, while up to 1000 I.U may be given to some elderly groups consuming uncleaved bread. Deficiency due to malabsorption states or liver disease often requires higher doses for treatment, of up to 1mg(40,000 I.U) daily. Doses of up to 2.5mg(100,000 I.U) daily may be used in the treatment of hypocalcaemia due to hypoparathyroidism. The dose is usually taken by mouth or through intramuscular route.

Availability:

Available in a pack of 10 ampoules.



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