"For Medical/Pharmacy Professionals Only"

Vitamin D_3 Injection I.P.
600000 I.U./ml

AMERICAN
Canrise D3
Injection
600000 I.U./ml
FOR IM USE ONLY

Composition :
Each ml Contains :

Cholecalciferol	I.P.	(600000 I.U.)	15 mg
Ethyl Oleate	I.P.		q.s.

Pharmaceutical Form
Dosage Form- Liquid Injection
Clinical Particulars
Therapeutic Indications
The prevention and treatment of vitamin D3 deficiency.
As an adjunct to specific therapy for osteoporosis in patients with vitamin D3 deficiency or at risk of vitamin D3 insufficiency.
Method of Administration
As directed by the physician.
Contra-Indications
• Hypersensitivity to the active substance(s) or to any of the excipients .
• Hypercalcaemia and/or hypercalciuria.
• Nephrolithiasis and/or nephrocalcinosis
• Serious renal impairment
• Hypervitaminosis D3
• Pseudohypoparathyroidism as the vitamin D3 requirement may be reduced due to phases of normal vitamin D3 sensitivity, involving the risk of prolonged overdose. Better-regulatable vitamin D3 derivatives are available for this.
Special Warnings and Precautions
Vitamin D3 should be used with caution in patients with impairment of renal function and the effect on calcium and phosphate levels should be monitored . The risk of soft tissue calcification should be taken into account.
Caution is required in patients receiving treatment for cardiovascular. It should be prescribed with caution in patients with sarcoidosis , due to a possible increase in the metabolism of vitamin D3 in its active form. In these patients the serum and urinary calcium levels should be monitored.
Drug Interactions
Concomitant use of anticonvulsants (such as phenytoin) or barbiturates (and possibly other drugs that induce hepatic enzymes) may reduce the effect of vitamin D3 by metabolic inactivation. Concomitant use of glucocorticoids can decrease the effect of vitamin D3. Vitamin D3 may interact with digitalis, cardiac glycosides, imidazole, cholestyramine, colestipol hydrochloride, orlistat or laxative such as paraffin oil.
Pregnancy
During pregnancy women should follow the advice of their medical practitioner as their requirements may vary depending on the severity of their disease and their response to treatment vitamin D3 and its metabolites are excreted in breast milk.
Lactation
Vitamin D3 can be prescribed while the patient is breast-feeding if necessary. This supplementation does not replace the administration of vitamin D3 in the neonate.
Side Effects
Some of the rare effects include pruritus, rash, and urticaria, Hypercalcaemia and hypercalciuria.
Overdose
Symptom
Colecalciferol (vitamin D3) have a relatively low therapeutic index, Overdose leads to increased serum and urinary phosphorus levels, as well as hyperca lcaemic syndrome and consequently calcium deposits in the tissues and above all in the kidneys (nephrolithiasis, nephrocatcinosis) and the vessels. Discontinue its use.
Treatment
Symptoms of chronic vitamin D3 overdosage may require forced diuresis as well as administration of glucocorticoids or calcitonin. Depending on the degree of hypercalcaemia, measures include a diet that is low in calcium or free of calcium, abundant liquid intake, increase of urinary excretion by means of the drug furosemide , as well as the administration of glucocorticoids and calcitonin. No special antidote exists.
Mechanism of action
In its biologically active form Vitamin D3 stimulates intestinal calcium absorption , incorporation of calcium into the osteoid , and release of calcium from bone tissue. In the small intestine it promotes rapid and delayed calcium uptake. The passive and active transport of phosphate is also stimulated . In the kidney, it inhibits the excretion of calcium and phosphate by promoting tubular resorption . The production of parathyroid hormone (PTH) in the parathyroids is inhibited directly by the biologically active form of vitamin D3. PTH secretion is inhibited additionally by the increased calcium uptake in the small intestine under the influence of biologically active vitamin D3.
Pharmacokinetic Properties
Absorption : Vitamin D3 is well absorbed from the gastro-intestinal tract in the presence of bile, so the administration with the major meal of the day might therefore facilitate the absorption of Vitamin D3.
Distribution & Biotransformation: It is hydroxylated in the liver to form 25-hydroxy-cholecalciferol and then undergoes further hydroxylation in the kidney to form the active metabolite 1, 25-dihydroxycholecalciferol (calcitriol).
Elimination
The metabolites circulate in the blood bound to a specific - globin, vitamin D3 and its metabolites are excreted mainly in the bile and faeces.

Storage : Store in a cool, dry & dark place. Protected from direct sunlight.

Improper storage may deteriorate the product.

Presentation : 6x1ml Ampoule in tray along with package insert. Such 5 carton in an outer carton.

Manufactured by:
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(An ISO 9001-2015 Certified Company)
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