Calciferol®

(Cholecalciferol USP 2, 00,000 IU/ml)

DESCRIPTION:
Calciferol® contains cholecalciferol (Vitamin D_3). It is required by the body in small amount for the smooth functioning of metabolic processes. It is involved in bone fixation of calcium.

COMPOSITION:
Each 1ml contains
Cholecalciferol USP (Vitamin D_3) 2,00,000 IU.

INDICATIONS:
Calciferol® is indicated in the prevention and treatment of Vitamin D_3 deficiencies. These are osteoporosis, osteomalacia, hypocalcaemia, tetany and rickets.

DOSAGE AND ADMINISTRATION:
By intramuscular injection.

Prevention:
Infants receiving Vitamin D enriched milk: ½ ampoule (0.5ml) i.e. 1,00,000 IU every 6 months.
Nursed infants or infants not receiving Vitamin D enriched milk or young children up to 5 years of age: 1 ampoule (1 ml) i.e. 2,00,000 IU every 6 months.

Adolescents:
1 ampoule (1ml) i.e. 2,00,000IU every 6 months.
Pregnancy: ½ ampoule (0.5 ml) i.e. 1,00,000IU from the 6th or 7th month of pregnancy.

Elderly: ½ ampoule (0.5ml) i.e. 1,00,000 IU every 3 months.

In digestive disorders, concomitant treatment with antiepileptics & other particular condition not described above:

½ ampoule (0.5ml) 1,00,000 IU or 1 ampoule (1ml) i.e. 2,00,000 IU every 3 or 6 months.

Vitamin D Deficiency:

1 ampoule (1 ml) i.e. 2,00,000 IU which can be repeated once 1 to 6 months later.

SIDE EFFECTS:

Individual tolerance to Vitamin D varies considerably. Infants and children are generally more susceptible to its toxic effects. Excessive administration of **Calciferol®** may lead to hypercalcaemia and hypervitaminosis. Hypervitaminosis is characterized by fatigue, loss of appetite, headache, and slimming, retardation of growth, nausea, vomiting, excess of urine, intense thirst and arterial hypertension.

CONTRA INDICATION:

Calciferol® should not be administered in case of hypercalcaemia and in patients who are hypersensitive to Vitamin D.

USE IN PREGNANCY AND LACTATION:
Calciferol® can be prescribed during pregnancy and lactation if necessary.

PRECAUTIONS:

It is advised that if possible women receiving **Calciferol®** do not feed their infants as this may lead to the development of hypercalcaemia of the infants. If high or repeated doses of **Calciferol®** are administered or if high doses of calcium are associated, it is necessary to monitor calcium levels in blood and urines.

WARNING:
Calciferol® must not be used in the following cases.
Hypersensitivity to Vitamin D
Hypocalcaemia (abnormally high blood calcium levels)
Hypercalciuria (excessive urinary elimination of calcium)
Calcium Lithiasis (Kidney stones)

DRUG INTERACTION:
Concomitant use of **Calciferol®** and following drugs may cause:

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.

Phenytoin/phenobarbital:
The coadministration of phenytoin or phenobarbital will not affect plasma concentrations of vitamin D, but may reduce endogenous plasma levels of calcitriol/ergocalcitriol by accelerating metabolism. Since blood level of calcitriol/ergocalcitriol will be reduced, higher doses of Rocaltrol may be necessary if these drugs are administered simultaneously.

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, precaution should be taken when coadministration 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 concentrations have been observed following the administration of 300 mg/day to 1200 mg/day ketoconazole for a week to healthy men. However, in vivo drug interaction studies of ketoconazole with vitamin D have not been investigated.

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 an 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 coadministration 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 hypermagnesium and should therefore not be taken during therapy with vitamin D by patients on chronic renal dialysis

STORAGE CONDITION:
Store in a cool and dry place, away from light and children.

PACKAGE QUANTITIES:
Ampoule of 1 ml x 1 in a carton.

® Trade Mark
Manufactured by
RENATA LIMITED
Mirpur, Dhaka,Bangladesh.
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