

Only for the use of Medical Professionals

D3[®]

Colecalciferol

Composition

D3[®] 2000 Tablet: Each coated tablet contains Colecalciferol (Vitamin D₃) BP 2000 IU.

D3[®] 20000 Capsule: Each capsule contains Colecalciferol (Vitamin D₃) BP 20000 IU.

D3[®] 40000 Capsule: Each capsule contains Colecalciferol (Vitamin D₃) BP 40000 IU.

D3[®] Oral Solution: Each ml contains Colecalciferol (Vitamin D₃) BP 200 IU.

D3[®] Injection: Each 1 ml ampoule contains Colecalciferol (Vitamin D₃) BP 200000 IU.

Pharmacology

D3[®] is the preparation of Colecalciferol which is a synthetic form of Vitamin D₃. The principal action of Vitamin D₃ is to increase intestinal absorption of both calcium and phosphate as well as regulate serum calcium, renal calcium and phosphate excretion, bone formation and bone resorption. Vitamin D₃ is essential for normal bone growth and development and to maintain bone density. It is also necessary for utilization of both calcium and phosphorus. Vitamin D₃ acts as a hormone and increases reabsorption of calcium and phosphorus by the kidney.

Indication

D3[®] is indicated for the prevention and treatment of colecalciferol (Vitamin D₃) deficiency of the following conditions-

- Bone disorders (such as rickets, osteomalacia)
- Prevent bone loss (such as osteoporosis)
- Low levels of calcium or phosphate caused by certain disorders (such as hypoparathyroidism, pseudohypoparathyroidism, familial hypophosphatemia and tetany caused by hypocalcaemia)
- During kidney disease to keep calcium levels normal and allow normal bone growth
- During pregnancy (6th or 7th month) and breastfeeding, an essential nutrient for a growing infant
- Pre-eclampsia during pregnancy
- Menopause

Dose and administration

Route of administration: **D3[®]** can be taken in oral and parenteral route.

D3[®] Capsule and Tablet

Adult

Treatment of vitamin D₃ deficiency: **D3[®]** Capsule 40000 IU/week for 7 weeks, followed by maintenance therapy **D3[®]** Tablet 1400-2000 IU/day for the next 3 to 4 months until target level of vitamin D₃ is achieved.

Prevention of vitamin D₃ deficiency: **D3[®]** Capsule 20000 IU/ month, or as directed by the physician.

Children (12 - 18 years)

Treatment of vitamin D₃ deficiency: **D3[®]** Capsule 20000 IU once every 2 weeks for 6 weeks.

Prevention of vitamin D₃ deficiency: **D3[®]** Capsule 20000 IU once every 6 weeks.

D3[®] Oral Solution

Up to one year: 400 IU once a day or as directed by the physician.

1 year to 18 years: 600 IU once a day or as directed by the physician.

D3[®] Injection

Injectable solution can be administered through IM or oral route.

For treatment:

Disease	Dosages
Rickets	1 ampoule every 2 weeks for one month then 1 ampoule for every 4 months
Osteoporosis	1 ampoule every 2 weeks for 3 months
Osteomalacia	1 ampoule every 2 weeks for 3 months
Tetany caused by hypocalcaemia	1 ampoule for every 4 months which may be increased to 2 ampoules
Menopause	1 ampoule for every 6 months
Vitamin D ₃ deficiency	1 ampoule can be repeated 1 to 6 months later

For prevention:

Period	Dosages
Pregnancy	1/2 ampoule at 6th or 7th months
During breastfeeding	1/2 ampoule for every 6 months
Children up to 5 years	1 ampoule for every 6 months
Adolescent	1 ampoule for every 6 months
Elderly	1/2 ampoule for every 3 months

Direction of use

For oral use	For IM use
Step-1: Place the thumb on ampoule and break the upper narrow part of the ampoule. Step-2: Pour out the solution of the ampoule in a spoon. Step-3: Mix the solution with water or milk before oral use.	Step-1: Place the thumb on ampoule and break the upper narrow part of the ampoule. Step-2: Then use as IM injection.

Contraindication

Colecalciferol is contraindicated in all diseases associated with hypercalcaemia. It is also contraindicated in patients with known hypersensitivity to colecalciferol and any components of the product. It is also contraindicated if there is vitamin D toxicity.

Warning and precaution

People with the following conditions should exercise with caution when considering taking vitamin D₃ supplements: high blood calcium or phosphorus level, heart problems and kidney disease. Vitamin D₃ must be taken with adequate amounts of both calcium and magnesium supplementation.

Side effects

Generally all nutritional supplements are considered to be safe and well tolerable. However, few most common side effects can generally occur including hypocalcaemia syndrome or calcium intoxication (depending on the severity and duration of hypocalcaemia), occasional acute symptoms include anorexia, headache, nausea, vomiting, abdominal pain or stomach ache and constipation with the administration of colecalciferol.

Use in pregnancy and lactation

It can be prescribed during pregnancy and lactation if necessary.

Use in children and adolescent

The guideline for children and adolescent is given in dose and administration.

Drug interaction

Drug interaction with medication: Concomitant treatment with phenytoin or barbiturates can decrease the effect of vitamin D because of metabolic activation. Concomitant use of glucocorticoids can decrease the effect of vitamin D. The effects of digitalis and other cardiac glycosides may be accentuated with the oral administration of calcium combined with vitamin D. Strict medical supervision is needed and, if necessary monitoring of ECG and calcium. Simultaneous treatment with ion exchange resins such as cholestyramine or laxatives such as paraffin oil may reduce the gastrointestinal absorption of vitamin D. The cytotoxic agent actinomycin and imidazole antifungal agents interfere with vitamin D activity by inhibiting the conversion of 25-hydroxyvitamin D to 1, 25-dihydroxyvitamin D by the kidney enzyme, 25-hydroxyvitamin D-1-hydroxylase.

Drug interaction with food and others: Not applicable.

Overdose

The most serious consequence of acute or chronic overdose is hypercalcaemia due to vitamin D toxicity. Symptoms may include nausea, vomiting, polyuria, anorexia, weakness, apathy, thirst and constipation. Chronic overdoses can lead to vascular and organ calcification as a result of hypercalcaemia. Treatment should consist of stopping all intakes of vitamin D and rehydration.

Storage

D3[®] Capsule, Tablet, Injection: Store in a cool and dry place protected from light. Keep away from the reach of children.

D3[®] Oral Solution: Store in a cool (below 25°C) and dry place protected from light. Keep away from the reach of children.

Packing

D3[®] 2000 Tablet: Carton of 30 tablets in blister pack.

D3[®] 20000 Capsule: Carton of 10 capsules in blister pack.

D3[®] 40000 Capsule: Carton of 12 capsules in blister pack.

D3[®] Oral Solution: Carton of 15 ml amber glass bottle.

D3[®] Injection: Carton of 1 ampoule in plastic tray.

® Registered Trade Mark



Advanced Chemical Industries Limited
7, Hajeegonj Road, Godnol
Narayangonj, Bangladesh