

Temcal-D[®]

Calcium & Vitamin D₃

COMPOSITION:

Temcal-D[®] Tablet: Each film coated tablet contains Calcium Carbonate USP 1250 mg equivalent to 500 mg elemental Calcium & Vitamin D₃ 200 IU as Cholecalciferol USP.

PHARMACOLOGY:

Adequate calcium in the blood is so vital to a wide variety of bodily functions that our internal biochemistry will not tolerate a deficiency even for short periods. Clinical evidence suggests that calcium is useful for the prevention and treatment of osteoporosis and associated fractures. Vitamin D is also essential for healthy bones as it aids in calcium absorption from the GI tract. In addition to this it stimulates bone formation. Clinical studies show that calcium and vitamin D has synergistic effects on bone growth as well as in osteoporosis and fracture prevention.

INDICATION:

Temcal-D[®] Tablet is used for the treatment of osteoporosis, osteomalacia, rickets, tetany and parathyroid disease. Also used in raised calcium requirement for children and adolescents at the times of rapid growth, inadequate intake of calcium in the diet due to malnutrition, prevention and treatment of osteoporosis, disorders of osteogenesis and tooth formation (in addition to specific treatment), latent tetany and during pregnancy and lactation. It is also used as routine supplement and phosphate binder in chronic renal failure.

DOSE & ADMINISTRATION:

The recommended dose of Temcal-D[®] Tablet is two tablet daily or 1 tablet in the morning and 1 tablet at night or as directed by the physician.

CONTRA-INDICATION:

- Hypercalcemia and hyperparathyroidism
- Hypercalciuria and nephrolithiasis
- Hypersensitivity to the component of this preparation
- Severe renal insufficiency
- Concomitant digoxin therapy (requires careful monitoring of serum calcium level)

WARNING AND PRECAUTION:

When hypercalcemia occurs, discontinuation of Temcal-D[®] Tablet is usually sufficient to return serum calcium concentrations to normal. Patients with a history of stone formation should also be recommended to increase their fluid intake.

SIDE EFFECTS:

Orally administered Calcium Carbonate may be irritating to the GI-tract. It may also cause constipation. Hypercalcemia is rarely produced by administration of calcium alone but may occur when large doses are given to patients with chronic renal failure. Also there may be allergic reactions, irregular heartbeats, nausea, vomiting, decreased appetite dry mouth and drowsiness. Following administration of vitamin-D supplements occasion skin rash has been reported.

USE IN PREGNANCY & LACTATION:

It should be used as directed by the physician during pregnancy and lactation.

USE IN CHILDREN & ADOLESCENTS:

Temcal-D[®] Tablet is not recommended for children and adolescents under 12 years of age.

DRUG INTERACTION:

Temcal-D[®] Tablet has possible interaction with digoxin, antacids containing calcium, aluminum or magnesium, other calcium supplements, calcitriol or other vitamin D supplements, tetracycline, Doxycycline, aminocycline or oxytetracycline etc. So before taking any of these drugs consultations of the physicians are needed.

OVERDOSE:

Symptoms of overdose may include nausea and vomiting, severe drowsiness, dry mouth, loss of appetite, metallic taste, stomach cramps, unconsciousness, diarrhea, weakness, headache, constipation, dizziness or irritability.

STORAGE:

Store in a dry and cool place below 30^o C temperature and keep away from light and moisture. Keep out of reach of children.

PACKING:

Temcal-D[®] Tablet Container: Each container contains 30's tablets.

Temcal-D[®] Tablet Strip: Each box contains 6x10's tablets in Alu-PVDC blister pack.



Manufactured by

Team Pharmaceuticals Ltd.

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