

Composition:

Fossical-DX Tablet: Each film coated tablet contains Calcium Carbonate (derived from coral fossil) USP 1500 mg equivalent to elemental Calcium 600 mg & Vitamin D₃, BP 400 IU as Cholecalciferol.

Pharmacology:

 $\label{eq:contains} \begin{tabular}{ll} Fossical-DX contains Coral Calcium and Vitamin D_3, where Coral Calcium is composed of Calcium Carbonate with small amounts of Magnesium and other trace minerals. Coral Calcium ensures better absorption than Calcium of other Calcium Carbonate preparations. Vitamin D_3, helps in the absorption of calcium from GI tract and helps, to maintain calcium balance in the body. \\ \end{tabular}$

Indications:

Fossical-DX is indicated in-

- the treatment and prevention of osteoporosis, rickets, osteomalacia, tetany and parathyroid disease.
- pregnancy & lactation due to increased demand.
- as phosphate binder in chronic renal failure.
- during therapy with anti-seizure medications.
- \bullet the prevention & treatment of calcium or vitamin $\mathrm{D_3}$ deficiency

specially in the housebound and institutional elderly patients.

Dosage & administration:

2 tablets per day, preferably one tablet in the morning and the other in the evening with plenty of water or as directed by the physician.

Contraindications:

Hypersensitivity to any component of the product. Hypercalcaemia for example, as a result of hyperparathyroidism, vitamin D_3 , overdose, severe renal insufficiency etc.

Precautions:

Careful monitoring with reduction of dose may be needed for patients with mild hypercalciuria. In case of mild to moderate renal impairment and for long term use plasma and serum calcium level should be monitored. Urinary calcium excretion should also be measured in patients with a history of renal stones to exclude hypercalciuria.

Side effects:

The most common side effects may include flatulence, nausea, gastric pain, diarrhea, skin rash etc. Hypercalciuria and hypercalcaemia may be occurred with long term treatment at high dosage.

Use in special groups: Use in pregnancy & lactation: Normal requirements of calcium & vitamin D_3 are raised during pregnancy & lactation. **Fossical-DX** can be given to pregnant women and lactating mother as per the recommendation of physician.

Drug interaction:

The risk of hypercalcaemia should be considered in patients taking thiazide diuretics since these drugs can reduce urinary calcium excretion. Oxalic acid, phosphate or phytanic acid containing foods may reduce the absorption of calcium. Concomitant treatment with phenytoin, barbiturates or glucocorticoids can decrease the effect of vitamin D_3 . The effects of digitalis and other cardiac glycosides may be accentuated with the oral administration of calcium combined with vitamin D_3 . Calcium salts may reduce the absorption of thyroxine, bisphosphonates, sodium fluoride, quinolone or tetracycline antibiotics or iron. It is advisable to allow a minimum period of four hours before taking the calcium.

Storage:

- Store below 30°C, protect from light & keep in dry place.
- Keep out of the reach of children.

Packing:

Fossical-DX Tablet: Each box contains 30 tablets in alu-alu blister pack.

