

Pharma code:
F-444 mini, B- 445 mini.

140 mm

For the Use of a Registered Medical Practitioner or a Hospital or a laboratory.

FAMCAL

Calcium Citrate Malate with Cholecalciferol Tablets

COMPOSITION

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Each film coated tablet contains:

Calcium Citrate Malate equivalent to	
Elemental Calcium.....	250mg
Cholecalciferol BP.....	100 IU

(as Stabilized D3)

Colour: Titanium Dioxide BP

Appropriate overages of vitamin added to compensate loss on storage

Excipients..... g.s.

CLINICAL PHARMACOLOGY

Pharmacodynamics. Calcium Citrate Malate (CCM) is a salt of citric and malic acid. These chelated forms of the Calcium correct an insufficient intake of calcium in the diet. It is also used as an adjunct in treatment and prevention of osteoporosis. Vitamin D3 corrects/Cholecalciferol: An insufficient intake of vitamin D and increases intestinal absorption of calcium. It is necessary for the regulation of calcium and phosphorus homeostasis and bone mineralization.

Pharmacokinetics

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Calcium Citrate Malate is well absorbed. Calcium is well distributed within skeletal tissues, breast milk and crosses placenta. Calcium is eliminated in the urine and faeces and secreted in the sweat.

Vitamin D3 is absorbed in the small intestine. Vitamin D3/Cholecalciferol and its metabolites circulate in the blood bound to a specific globulin. Cholecalciferol is converted in the liver by hydroxylation to the active form 25-hydroxycholecalciferol. It is then further converted in the kidneys to 1,25 dihydroxycholecalciferol. 1,25 dihydroxycholecalciferol is the metabolite responsible for increasing calcium absorption. Vitamin D which is not metabolised is stored in adipose and muscle tissues. Vitamin D is excreted in faeces and urine.

INDICATIONS

FAMCAL is indicated for Supplementation of calcium and Vitamin D during pregnancy and lactation. It is also indicated for treatment and prevention of osteoporosis.

CONTRAINDICATIONS

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FAMCAL is contraindicated in patient with hypersensitivity to the active substances or to any of the excipients. It should not be given in diseases and/or conditions resulting in hypercalcaemia and/or hypercalciuria (e.g. myeloma, bone metastases, primary hyperparathyroidism). It is also contraindicated in nephrolithiasis, nephrocalcinosis and renal failure.

WARNINGS AND PRECAUTIONS

During long-term treatment, serum and urinary calcium levels should be followed and renal function should be monitored through measurements of serum creatinine. In patients with a history of renal stones urinary calcium excretion should be measured to exclude hypercalciuria. Patients with mild to moderate impairment of renal function should be supervised carefully.

Drug Interactions

Some products that may interact with **FAMCAL** : digoxin, phosphate binders, thiazide diuretics (e.g., hydrochlorothiazide). Calcium can decrease the absorption of other drugs such as tetracycline antibiotics (e.g., doxycycline, minocycline), bisphosphonates (e.g., alendronate), estramustine, levothyroxine, and quinolone antibiotics (e.g., ciprofloxacin, levofloxacin). Certain medications can decrease the absorption of vitamin D (bile acid sequestrants such as colestyramine/colestipol, mineral oil, orlistat).

Pregnancy

FAMCAL can be given during pregnancy in cases of calcium and vitamin D3 deficiency. Therapy should be under medical supervision.

Lactation

FAMCAL can be used during breast-feeding. Calcium and vitamin D pass into breast milk. This should be considered when giving additional vitamin D/calcium to the child.

Pediatric Use

FAMCAL is not intended for use in children.

ADVERSE EFFECTS

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Constipation, headache, nausea, muscle weakness, hypercalcemia, hypercalciuria and abdominal pain.

DOSAGE AND ADMINISTRATION

1 to 2 Tablets daily or as directed by the physician.

STORAGE AND HANDLING INSTRUCTIONS

Store below 30°C, Protect from light

PRESENTATION

Blister pack of 2 x 15's Tablets

Manufactured by:

INDOCO REMEDIES LTD.
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