

For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory

SHELCAL M
(Calcium carbonate, Vitamin D₃ and Minerals)

COMPOSITION

Shelcal M

Each film-coated tablet contains:

1250 mg Calcium Carbonate from an organic source (Powdered Oyster Shell) equivalent to

Elemental Calcium..... 500 mg

Vitamin D₃ I.P..... 250 IU

Magnesium (Elemental) as Magnesium Oxide I.P.....40 mg

Manganese (Elemental) as Manganese Sulfate U.S.P. 1.8 mg

Zinc (Elemental) as Zinc Sulphate I.P..... 7.5 mg

Copper (Elemental) as Cupric Sulfate U.S.P.....1.0 mg

Boron as Sodium Borate B.P..... 250 mcg

Colours: Lake of Brilliant Blue FCF, Titanium Dioxide I.P. & Mica Based Pearlescent Pigments

Appropriate overages of vitamins added to compensate for loss on storage.

DOSAGE FORM

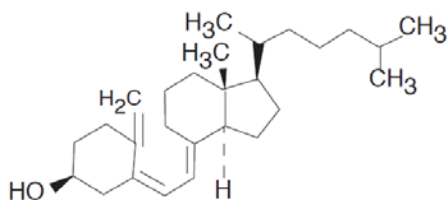
Film-coated tablet for oral use.

DESCRIPTION

Shelcal M is a film coated tablet that combines the calcium carbonate derived from the oyster shell along with vitamin D₃, mineral and trace elements necessary for situations requiring therapeutic supplementation. Shelcal M offers the additive benefits of trace elements along with vitamin D₃ in maintenance of bone health.

Vitamin D₃ (Cholecalciferol)

Cholecalciferol is the naturally occurring form of Vitamin D₃. It is produced from 7-dehydro cholesterol, a sterol present in mammalian skin, by ultraviolet irradiation. Its empirical formula is C₂₇H₄₄O, and molecular weight is 384.6. It is chemically as (5Z,7E)-(3S)-9,10- secocholesta-5,7,10(19)-triene-3-ol.



Calcium

Calcium is a mineral that is present naturally in the food. It is necessary for many normal functions of body mainly, bone formation and maintenance.

CLINICAL PHARMACOLOGY

PHARMACODYNAMIC

Calcium is the major constituent found in the various part of the body. e.g. bone, teeth etc. Calcium carbonate plays a critical role in the formation of bone, in chronic renal failure patients; calcium carbonate is used as a phosphate binding agent. Calcium carbonate has three main actions: it neutralizes gastric acid, supplements dietary calcium and sequesters phosphorus in the intestine.

Vitamin D₃ is cholecalciferol, the naturally occurring form of vitamin D. After absorption, it is rapidly hydroxylated to calcitriol, active form of vitamin D. It enhances the absorption of calcium hence it is commonly prescribed along with various bone diseases or as nutritional supplement during adolescence and pregnancy and lactation.

Minerals and trace elements other than calcium are involved in skeletal growth,

Magnesium: Magnesium is involved in bone and mineral homeostasis and is important in bone crystals growth and stabilization. Magnesium is a cofactor in more than 300 enzymatic reactions and plays a major role in bone cell function and hydroxyapatite crystallization and growth.

Manganese: It is cofactor for several enzymes, it assist bone formation and pyruvate conversion.

Zinc: It is cofactor for several enzymes. It is essential for synthesis of nucleic acid, protein metabolism and cell membrane. It also play role in wound healing, immune function, growth, development of sexual organs and bones, insulin function, it is component of superoxide dismutase.

Copper: It is an essential component of the enzymatic systems involved in bone matrix turnover. Copper improves synthesis of collagen which is an important component of connective tissues.

Boron: Boron play role in skeletal growth and may have key role in brain activities.

PHARMACOKINETICS

After oral administration Calcium, vitamin D₃ and mineral were well absorbed from the intestine, utilized for various biochemical reactions and are excreted out in urine, sweat, faeces and bile.

Calcium Carbonate: Calcium Carbonate is well absorbed from the GI tract in the presence of gastric acid where it is converted to calcium chloride. Calcium carbonate is absorbed as free calcium and bicarbonate ions. Approximately half the calcium in serum is protein bound 5-10% complexed in the form of small readily diffusible organic salts and the remainder as free ions.

Vitamin D₃: Vitamin D₃ which is completely absorbed from the small intestine enhances the absorption of calcium.

Magnesium: The efficacy of magnesium absorption varies widely from 35% to 45%. Magnesium may be absorbed along the length of the small intestine, but most absorption occurred in the jejunum. The efficacy of the absorption varies with the magnesium in the diet, and the constipation of the diet as whole.

Manganese: Manganese is absorbed throughout the small intestine. Manganese is transported bound to a macroglobulin, transferrin and transmanganin.

Zinc: The absorption of zinc is by two pathways similar to those of calcium. A saturable carrier mechanism involving para-cellular movement at high zinc intakes. Zinc absorption is affected by the level of zinc in the diet and presence of interfering substances especially phytates.

Copper: It is absorbed after oral administration from GIT. It is an essential component of the enzymatic systems involved in bone matrix turnover.

Boron: It is a ultra- trace element obtained from food as sodium borate. Boron is rapidly and almost completely absorbed.

INDICATIONS

Shelcal-M Tablet is indicated as a calcium and mineral supplement in deficiency states i.e. during growth, Pregnancy and lactation, prevention and treatment of osteoporosis.

DOSAGE AND ADMINISTRATION

The oral dose is one tablet twice daily or as directed by the physician.

CONTRAINDICATION

Absolute contra-indications are hypercalcaemia resulting from myeloma, bone metastases or other malignant bone disease, sarcoidosis, primary hyperparathyroidism, vitamin D over-dosage and severe renal failure, Hypersensitivity to any of the tablet ingredients.

WARNING AND PRECAUTIONS

Patients with mild to moderate renal failure or mild hypercalciuria should be supervised carefully including periodic checks of plasma calcium levels and urinary calcium excretion.

In the patients with a history of renal stones urinary calcium excretion should be measured to exclude hypercalciuria.

With long-term treatment it is advisable to monitor serum and urinary calcium levels and kidney function, and reduce or stop treatment temporarily if urinary calcium exceeds 7.5 mmol/ 24 hours (300mg/24 hours).

DRUG INTERACTIONS

Thiazide diuretics: The risk of hypercalcaemia should consider in patients taking thiazide diuretics since these drugs can reduce urinary calcium excretion.

Hypercalcaemia must be avoided in digitalized patients. Certain foods (e.g. those containing oxalic acid, phosphate or phytinic acid) may reduce the absorption of calcium.

Phenytoin or barbiturates: Concomitant treatment with phenytoin or barbiturates can decrease the effect of vitamin D because of metabolic activation.

Glucocorticoids: Concomitant use of glucocorticoids can decrease the effect of vitamin D.

Digitalis and other cardiac glycosides: The effects of digitalis and other cardiac glycosides may accentuated with the oral administration of calcium combined with vitamin D. Strict medical supervision is needed and, if necessary monitoring of ECG and calcium is required.

Calcium salts may reduce the absorption of thyroxine, bisphosphonates, sodium fluoride, quinolone or tetracycline antibiotics or iron.

Renal Impairment

Although only small amounts of a vitamin D dose are recovered in the urine, metabolic conversion to calcitriol is reduced and higher doses are generally required in most conditions.

Hepatic Impairment

Pharmacokinetic data are lacking. However, intestinal absorption may be markedly impaired; conversion to 25 OHD may also be reduced significantly, with the requirement of high doses.

Pregnancy and Lactation

During pregnancy and lactation treatment with Shelcal- M should be under the supervision of a physician.

Over doses of vitamin D have shown teratogenic effects in pregnant animals. However, there have been no studies on the use of this medicinal product in human pregnancy and lactation. Vitamin D and its metabolites pass into the breast milk.

Geriatric Use

In the treatment of ostomalacia, daily doses of 1000 international units of vitamin D₃ significantly increase calcium absorption in patients below the age of 70 years.

ADVERSE REACTIONS

Generally, Shelcal- M Tablets is well tolerated. However, some individuals shown mild & transient effects on GIT, CVS & Renal system which are follow:

G.I.T.: The most frequency reported side-effects resulting from postmarketing experience with Calcium with vitamin D₃ and mineral formuations were gastrointestinal and include abdominal pain, vomiting, flatulence, nausea, constipation.

Hepatic: None

CNS: None

Cardiovascular: Tachycardia and palpitation.

Haematological: None

Renal: None. The higher doses of calcium with vitamin D₃ have been associated with hypercalciuria.

Hypersensitivity Reaction (Allergic): None. Some patients may cllicit allergic reactions those who are hypersensitive to any of the ingredient of formulation.

OVERDOSAGE

Acute or long-term overdose can cause hypervitaminosis D and hypercalcaemia. Hypercalcaemia gives the following symptoms: nausea, vomiting, thirst, polydipsia, polyuria, constipation. Chronic overdose can lead to vascular and organ calcification as a result of hypercalciamia.

Treatment

Treatment is symptomatic and supportive. All treatment with calcium and vitamin D should be rehydration should be performed.

EXPIRY DATE

Do not use later than the date of expiry.

STORAGE

Store in a cool dry place below 25°C

PRESENTATIONS

Shelcal-M is available in blister pack of 15 Tablets

MARKETED BY:



TORRENT PHARMACEUTICALS LTD.

Torrent House, Off Ashram Road,

Ahmedabad-380 009, INDIA