

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

SHELCAL OS
(Calcium with Alfacalcidol Tablets)

COMPOSITION

SHELCAL OS

Each film-coated tablet contains:

1250 mg Calcium Carbonate from an organic source (Powdered Oyster Shell) equivalent to Elemental Calcium 500 mg

Alfacalcidol I.P. 0.25 mcg

Colours: Lake of Quinoline Yellow WS, Lake of Brilliant Blue FCF and Titanium Dioxide I.P.
Appropriate overages of vitamins added to compensate for loss on storage.

DESCRIPTION

Shelcal OS is a film coated tablet that combines the calcium carbonate derived from the oyster shell alone with Alfacalcidol necessary for situations requiring therapeutic supplementation. Calcium Carbonate derived from oyster shell contains higher proportion of elemental calcium (40% elemental calcium) and has better tolerability profile. Alfacalcidol is an analogue of vitamin D which is fat soluble and helps to increase the intestinal absorption of calcium.

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.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic Property

Calcium is the major consultant found in various parts of human body, e.g. bone, teeth etc. Calcium carbonate is well as an antacid. In chronic renal failure patients, calcium carbonate is used as a phosphate-binding agent. Calcium carbonate has three main actions its neutralizes gastric acid supplements dietary calcium and sequesters phosphorus in the intestine.

Alfacalcidol is converted rapidly in the liver to 1.25 dihydroxy Vitamin D. This is the metabolite Vitamin D which acts as a regulator of calcium and phosphate metabolism.

Pharmacokinetic property

After oral Administration Calcium and Alfacalcidol are well absorbed from the intestine, utilized for various biochemical reactions and are excreted out in urine, sweat, faces 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.

Alfacalcidol: It is fat soluble and up to 100% absorption normally takes place. After absorption alfacalcidol is rapidly hydroxylated at the 25 position, predominantly in the liver. It is transported in plasma by a – globulin. In the normal situation it controls the intestinal absorption of calcium and phosphates and plays an important part in the regulation of bone mineralization. It is excreted in the bile, urine or the faeces.

INDICATIONS

Shelcal OS Tablet is indicated as a calcium supplement in deficiency states i.e. during growth, prevention and adjunct treatment of senile, postmenopausal and corticosteroid induced osteoporosis.

DOSAGE AND ADMINISTRATION

The oral dose is one to two tablets 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).

Caution is required in patient receiving the treatment for cardiovascular disease.

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.

DRUG INTERACTIONS

Thiazide diuretics: The risk of hypercalcaemia should be considered 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 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 is required.

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

ADVERSE REACTIONS

Generally, Shelcal OS Tablets is well tolerated. However, some individuals show mild & transient effects on GIT, CVS & Renal system which are as follows:

G.I.T.: The most frequently reported side-effects resulting from postmarketing experience with Calcium with vitamin D₃ and mineral formulations 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 elicit allergic reactions those who are hypersensitive to any of the ingredients of formulation.

OVERDOSAGE

Acute or long-term overdose can cause hyper vitaminosis 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 hypercalcaemia.

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
Protect from light

PRESENTATIONS

Shelcal OS is available in blister pack of 15 Tablets

MARKETED BY:



TORRENT PHARMACEUTICALS LTD.

Torrent House, Off Ashram Road,
Ahmedabad-380 009, INDIA