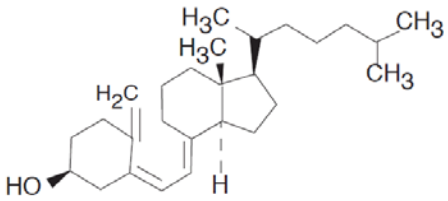
For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory

SHELCAL CT
(Calcium with Calcitriol tablets)

COMPOSITION
SHELCAL CT
Each film-coated tablet contains:
1250 mg Calcium Carbonate from an organic source (Powdered Oyster Shell) equivalent to Elemental Calcium 500 mg
Calcitriol I.P. 0.25 mcg
Colors: Titanium Dioxide I.P. and Mica Based Pearlescent Pigments
Appropriate overages of vitamins added to compensate for loss on storage

DESCRIPTION:
Shelcal CT is a film coated tablet that combines the calcium carbonate derived from the oyster shell along with additive benefits of calcitriol in maintenance of bone health.

Vitamin D3 (Cholecalciferol)
Cholecalciferol is the naturally occurring form of Vitamin D_3. It is produced from 7-dehydro cholesterol, a sterol present in mammalian skin, by ultraviolet irradiation. It's empirical formula is $C_{27}H_{44}O$, 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.

PHARMACOLOGICAL CATEGORY:
Calcium and vitamin supplement

PHARMACEUTICAL FROM:
Tablet

PHARMACOLOGICAL PROPERTIES:
Pharmacodynamics Property
Calcium is a major constituent found in various parts of human body, e.g. bones, teeth etc. Calcium carbonate is well known as an antacid. 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 as sequesters phosphorus in the intestine.

Calcitriol or 1.25 dihydroxy cholocalciferol (abbreviated 1,25-(OH)2D3) is the active from of vitamin D found in the body (vitamin D3), which is active in the regulation of the absorption of calcium from the gastrointestinal tract and its utilization in the body. The direct influence of calcitriol is increasing the uptake of dietary calcium into the blood, but also the uptake of calcium into the bones (Calcitriol) therefore also stimulates osteoblast activity and thus increases osteoblasts apoptosis and deportation of calcium from bones. Hence it is commonly prescribed along with calcium in people with various bone diseases or as nutritional supplement.

Pharmacokinetic Property
After oral administration Calcium and Calcitriol were well absorbed from the intestine, utilized for various biochemical reactions and are excreted out in urine, sweat, faces and bile.

Calcium Carbonate: Calcium Carbonates 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 bicarbonate ions. Approximately half the calcium in serum is protein bound 5-10% complexes. In the form of small readily diffusible organic salts and the remainder as free ions.

Calcitriol: Cacitriol is completely absorbed from the small intestine and enhances the absorption of calcium. Cacitriol is approximately 99.9% bound in blood. Calcitriol and other vitamin D metabolites are transported in blood by an alpha-globulin vitamin D binding protein. Calcitriol catabolized to calcitroic acid. Calcitriol is excreted in the bile and it subject to enterohepatic circulation.

INDICATION:
SHELCAL-CT tablets is indicated as a vital calcium supplement in deficiency states i.e. during growth, prevention and adjunct treatment of senile, post-menopausal and corticosteroid induced osteoporosis.

DOSAGE AND ADMINISTRATION:
The oral dose is one tablet twice daily or as directed by the physician.

CONTRA-INDICATIONS:
- Absolute contra-indications are hypercalciuria and hypercalcemia and diseases or conditions resulting in hypercalcemia and/ or hypercalciuria (e.g. myeloma, bone metastases, primary hyperparathyroidism).
- Hypersensitivity to calcium, calcitriol or to any of the excipients.
- Kidney stones (nephrolithiasis, nephrocalciosis)
- Severe renal impairment and renal failure.
- Hypervitaminosis D

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 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 patients receiving treatment for cardiovascular disease.

DRUG INTERACTIONS:
Thiazide diuretics: The risk of hypercalcamia 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.

Calcium salts may reduce the absorption of *thyroxine, bisphosphonates, sodium fluoride, quinolonger or tetracycycline antibiotics or iron*. It is advisable to allow a minimum period of four hours before taking the calcium.

PREGNANCY AND LACTATION:
Shelcal CT should be used during pregnancy only if the benefits outweigh the potential risk to the fetus. During pregnancy and lactation treatment with Shelcal-CT should always be under the supervision of a physician.

Overdoses 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 to breast milk.

ADVERSE REACTIONS:
Generally, **Shelcal CT** tablets are well tolerated. However, some individuals shown mild and transient effects on GIT, CVS & Renal system which are as follows-

G.I.T.: The most frequently reported side-effects resulting from the post-marketing experience with calcium with calcitriol formulations were gastrointestinal and include abdominal pain, vomiting, flatulence, nauseas constipations.

Hepatic: None

C.N.S.: None

Cardiovascular: Tachycardia and palpitation.

Hematological: None

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

Hypersensitivity Relation (Allergic): Patients hypersensitive to any of the ingredient may elicit allergic reactions.

OVERDOSE

Since calcitriol is a derivative of vitamin D acute or long-term overdose can cause hypervitaminosis D and hypercalcaemia gives the following symptoms: nausea, vomiting: thirst, polidipsia, polyuria, constipation, chronic overdoses 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 interrupted and rehydration should be performed.

EXPIRY DATE

Do not use later than the date of expiry.

STORAGE

Store below 25 ^{o}C. Protect from moisture. Keep Out Of Reach of Children.

PRESENTATIONS

Shelcal CT is available in blister pack of 15 Tablets.

MARKETED BY:

TORRENT PHARMACEUTICALS LTD.
Torrent House, Off Ashram Road,
Ahmedabad-380 009, INDIA