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

SHELCAL CM

1. Generic Name

Calcium and Vitamin D3 Tablet I.P.

2. Qualitative and quantitative Composition:

SHELCAL CM

Each Film Coated Tablet contains :

Calcium Citrate Malate I.P.

Eq. to Elemental Calcium …… 250 mg

Vitamin D3 I.P. ……... 1000 IU

Colour: Titanium Dioxide I.P.

Appropriate overages of vitamin added to compensate the loss on storage.

The excipients used are Hydroxy Propyl Methyl Cellulose, Polyethylene Glycol, Titanium Dioxide, Talcum Powder, Colloidal Silicon Dioxide, Magnesium Stearate, Sodium Starch Glycolate and Starch.

3. Dosage form and strength

Dosage form: Film coated tablet.

Strength: 250 mg + 1000 IU

4. Clinical particulars

4.1. Therapeutic indication

It is indicated for the treatment of calcium and mineral deficiency.

4.2. Posology and method of administration

Posology

One tablet daily or as directed by the physician.

Method of administration

Tablet should be taken orally.

4.3. Contraindications

Absolute contra-indications are hypercalcaemia resulting for example from myeloma, bone metastases or other malignant bone disease, sarcoidosis; primary hyperparathyroidism and vitamin D overdosage. Severe renal failure.

Hypersensitivity to the active substance or to any of the excipients.

Relative contra-indications are osteoporosis due to prolonged immobilisation, renal stones, and severe hypercalciuria.

4.4. Special warnings and precautions for use

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 7.5mmol/24 hours (300mg/24 hours).

Should be prescribed with caution to patients with increased risk of hypercalcaemia e.g. patients with sarcoidosis or those suffering from malignancies.

Use with caution in the elderly and debilitated and in patients with impaired liver function. as hypermagnesaemia may result.

The possibility of manganese retention should be a consideration in patients with biliary obstruction and caution should be exercised since manganese is eliminated via the bile.

Hormone-sensitive condition such as breast cancer, uterine cancer, ovarian cancer, endometriosis, or uterine fibroids: Boron might act like estrogen. If you have any condition that might be made worse by estrogen, avoid supplemental boron or high amounts of boron from foods.

4.5. Drugs interactions

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 digitalised patients.

Certain foods (e.g. those containing oxalic acid, phosphate or phytinic acid) may reduce the absorption of calcium.

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

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, quinolone or tetracycline antibiotics or iron. It is advisable to allow a minimum period of four hours before taking the calcium.

Magnesium hydroxide may interfere locally with the absorption of other drugs taken orally by increasing gastric pH. This can be avoided by giving other drugs 2-3 hours before the administration of magnesium hydroxide on the advice of a doctor.

Large doses of zinc decrease the absorption of tetracyclines by the formation of an insoluble chelate and the absorption of zinc may be reduced by penicillamine.

4.6. Use in special populations (such as pregnant women, lactating women, paediatric patients, geriatric patients etc.)

During pregnancy and lactation treatment should always be under the direction of a physician. During pregnancy and lactation, requirements for vitamins and mineral supplements are increased but in deciding on the required supplementation allowances should be made for availability of these agents from other sources. If calcium containing tablets and iron supplements are both required to be administered to the patient, they should be taken at different times.

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. In humans, long term hypercalcaemia can lead to physical and mental retardation, aortic stenosis and retinopathy in a newborn child. Vitamin D and its metabolites pass into the breast milk.

4.7. Effects on ability to drive and use machines

No data is available regarding the effects on ability to drive and use machines.

4.8. Undesirable effects

Frequency estimate: Very common (≥ 1/10); common (≥ 1/100 to < 1/10); uncommon (≥ 1/1,000 to < 1/100); rare (≥ 1/10,000 to < 1/1,000); very rare (< 1/10,000), not known (cannot be estimated from the available data).

Immune system disorders

Not known: Hypersensitivity reactions such as angio-oedema or laryngeal oedema.

Metabolism and nutrition disorders

Uncommon: Hypercalcaemia and hypercalciuria.

Very rare: Seen usually only in overdose: Milk-alkali syndrome.

Gastrointestinal disorders

Rare: Constipation, dyspepsia, flatulence, nausea, abdominal pain and diarrhoea.

Skin and subcutaneous disorders

Rare: Pruritus, rash and urticaria.

Reporting of adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Report suspected adverse reactions via any point of contact available at www.torrentpharma.com or at email: pv@torrentpharma.com or call on 1800-120-3001.

4.9. Overdose

Calcium and vitamin D3:

Overdose can lead to hypervitaminosis D and hypercalcaemia.

Symptoms of hypercalcaemia may include anorexia, thirst, nausea, vomiting, constipation, abdominal pain, muscle weakness, fatigue, mental disturbances, polydipsia, polyuria, bone pain, nephrocalcinosis, nephrolithiasis and in severe cases, cardiac arrhythmias. Extreme hypercalcaemia may result in coma and death. Persistently high calcium levels may lead to irreversible renal damage and soft tissue calcification. Milk-alkali syndrome may occur in patients who ingest large amounts of calcium and absorbable alkali.

Treatment of hypercalcaemia the treatment with Calcium and Vitamin D3 must be discontinued. Treatment with thiazide diuretics, lithium, vitamin A and cardiac glycosides must also be discontinued. Treatment is rehydration, and, according to severity of hypercalcaemia, isolated or combined treatment with loop diuretics, bisphosphonates, calcitonin and corticosteroids should be considered. Serum electrolytes, renal function and diuresis must be monitored. In severe cases, ECG and CVP should be followed.

5. Pharmacological properties

5.1. Mechanism of Action

Calcium Citrate Maleate:

Calcium Citrate Maleate dissociates in the gastrointestinal tract to release free calcium ions, which are readily absorbed through both active, vitamin D–dependent transport in the duodenum and passive diffusion throughout the small intestine. The citrate and maleate components enhance calcium solubility and absorption, even in individuals with low stomach acid. Once absorbed, calcium enters the bloodstream and contributes to various physiological functions. It supports bone formation by supplying calcium for hydroxyapatite crystal development, suppresses parathyroid hormone (PTH) secretion by increasing serum calcium levels, and reduces bone resorption. Additionally, calcium ions participate in muscle contraction, nerve conduction, enzyme activation, and blood clotting. The overall action of CCM is to restore and maintain calcium homeostasis, promote bone mineralization, and support normal neuromuscular and cardiovascular functions.

Vitamin D3:

The in vivo synthesis of the predominant two biologically active metabolites of vitamin D occurs in two steps. The first hydroxylation of vitamin D3 cholecalciferol (or D2) occurs in the liver to yield 25-hydroxyvitamin D while the second hydroxylation happens in the kidneys to give 1, 25-dihydroxyvitamin D.

5.2. Pharmacodynamic properties

Calcium Citrate Maleate:

Calcium Citrate Maleate (CCM) is a highly bioavailable calcium salt used primarily to support bone health. Upon ingestion, it dissociates to release calcium ions, which are absorbed efficiently in both acidic and neutral gastrointestinal environments due to the presence of citrate and maleate, enhancing solubility. Once absorbed, calcium plays essential roles in bone mineralization, muscle contraction, nerve transmission, blood clotting, and intracellular signaling. Increased serum calcium from CCM intake suppresses parathyroid hormone (PTH) secretion, thereby reducing bone resorption and promoting calcium retention in bones. Citrate also helps prevent kidney stone formation by binding urinary oxalate. Overall, CCM exerts its pharmacodynamic effects by restoring and maintaining calcium homeostasis, especially beneficial in populations at risk of osteoporosis or low calcium absorption.

Vitamin D3:

Cholecalciferol, also called as vitamin D3, is produced naturally by ultraviolet irradiation of the provitamin, 7-dehydrocholesterol (a precursor of vitamin D) in the skin. Absorbed cholecalciferol requires metabolic activation. The circulating vitamin undergoes hydroxylation in the liver with the help of the enzyme, vitamin D 25-hydroxylase to form 25-hydroxycholecalciferol (calcidiol), which is the predominant circulating metabolite. Further hydroxylation in the kidneys (in response to need for phosphorus and calcium) forms 1,25-dihydroxycholecalciferol (calcitriol) with the help of 1alpha-hydroxylase. Calcidiol possesses some intrinsic activity, but calcitriol is the most active vitamin D metabolite with respect to initiating intestinal transport of calcium and phosphate and mobilizing calcium from bone. Calcitriol may prevent phosphaturia by inhibiting parathyroid hormone secretion. Conversion to calcitriol is stimulated by the parathyroid hormone, as well as decreases in serum inorganic phosphate levels. Reduced renal conversion of calcidiol to calcitriol contributes to altered calcium haemostasis and osteodystrophy in uraemia

5.3. Pharmacokinetic properties

Calcium Citrate Maleate:

Absorption: The amount of calcium absorbed through the gastrointestinal tract is approximately 30% of the swallowed dose.

Distribution and metabolism:99% of the calcium in the body is concentrated in the hard structure of bones and teeth. The remaining 1% is present in the intra - and extracellular fluids. About 50% of the total blood-calcium content is in the physiologically active ionised form with approximately 10% being complexed to citrate, phosphate or other anions, the remaining 40% being bound to proteins, principally albumin.

Elimination: Calcium is eliminated through faeces, urine and sweat. Renal excretion depends on glomerular filtration and calcium tubular reabsorption.

Vitamin D3:

Absorption: Vitamin D3 is easily absorbed in the small intestine.

Distribution and metabolism: Vitamin D3 and its metabolites circulate in the blood bound to a specific globulin. Vitamin D3 is converted in the liver by hydroxylation to the active form 25-hydroxycholecalciferol. It is then further converted in the kidneys to 1,25 hydroxycholecalciferols; 1,25 hydroxycholecalciferol is the metabolite responsible for increasing calcium absorption. Vitamin D3 which is not metabolised is stored in adipose and muscle tissues.

Elimination: Vitamin D3 is excreted in faeces and urine.

6. Nonclinical properties

6.1. Animal Toxicology or Pharmacology

No data on animal studies of safety pharmacology available.

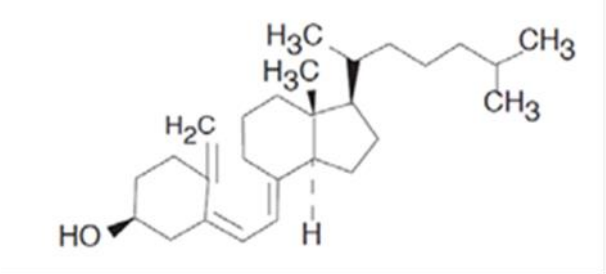
7. Description

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.

Vitamin D3 (Cholecalciferol)

Cholecalciferol is (5Z,7E)-(3S)-9,10- secocholesta5,7,10(19)-triene-3-ol. Its empirical formula is $C_{27}H_{44}O$, and molecular weight is 384.6. The chemical structure of Cholecalciferol is:



SHELCAL CM

Calcium and Vitamin D Tablets are white to off white coloured, elongated, biconvex, one side scored, plain on other side.

The excipients used are Hydroxy Propyl Methyl Cellulose, Polyethylene Glycol, Titanium Dioxide, Talcum Powder, Colloidal Silicon Dioxide, Magnesium Stearate, Sodium Starch Glycolate and Starch.

8. Pharmaceutical particulars

8.1. Incompatibilities

Not applicable

8.2. Shelf-life

Do not use later than the date of expiry.

8.3. Packaging information

SHELCAL CM is packed in Blister strip of 15 tablets

8.4. Storage and handing instructions

Store protected from light & moisture at a temperature not exceeding 25°C.

Keep out of reach of children.

9. Patient Counselling Information

Ask the patients to inform the treating physicians in case of any of the below:

- Have any allergies
- Have kidney or liver problems
- Are pregnant or plan to become pregnant
- Are breastfeeding or plan to breastfeed
- Have any serious illness
- Are taking any medicines (prescription, over-the-counter, vitamins, or herbal products)

10. Details of manufacturer

Pure & Cure Healthcare Pvt. Ltd.

(A subsidiary of Akums Drugs & Pharmaceuticals Ltd.)

Plot No. 26A, 27-30,Sector-8A, I.I.E, SIDCUL, Ranipur, Haridwar -249 403, Uttarakhand.

11. Details of permission or licence number with date

Mfg. Lic. No: 51/UA/SC/P-2013, Issued on 27.09.2022

12. Date of revision

JUN-2026

MARKETED BY

TORRENT PHARMA

TORRENT PHARMACEUTICALS LTD.

IN/SHELCAL CM (250 mg +1000 IU)/JUN 2026/02/PI