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

SHELCAL CT

1. Generic Name

Calcium with Calcitriol tablets

2. Qualitative and quantitative Composition:

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

Colours: Titanium Dioxide I.P. and Titanium Dioxide Coated Mica Pearlescent Pigments

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

The excipients used are Gelatin, Sodium Methyl Paraben, Propyl Paraben Sodium, Crospovidone, Talc, Starch, Microcrystalline Cellulose, Butylated Hydroxy Anisole, Butylated Hydroxy Toluene, magnesium Stearate, Instacoat Aqua, Instacoat Smart.

3. Dosage form and strength

Dosage form: Film coated tablets

Strength: 500 mg + 0.25 mcg

4. Clinical particulars

4.1. Therapeutic indication

For the treatment of hypocalcaemia and/or osteoporosis.

4.2. Posology and method of administration

Posology

There is no relevant use of abiraterone in the paediatric population.

Method of administration

Oral use.

4.3. Contraindications

- 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

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 7.5 mmol/24 hours (300mg/24 hours). Caution is required in patients receiving treatment for cardiovascular disease.

4.5. Drugs 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.

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

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.

4.7. Effects on ability to drive and use machines.

On the basis of the pharmacodynamic profile of reported adverse events, this product is presumed to be safe or unlikely to adversely affect such activities.

4.8. Undesirable effects

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.

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.

4.9. 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.

5. Pharmacological properties

5.1. Mechanism of Action

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.

5.2. Pharmacodynamic properties

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.

5.3. Pharmacokinetic properties

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.

6. Nonclinical properties

6.1. Animal Toxicology or Pharmacology

Calcium Carbonate

There is no information of relevance to the safety assessment.

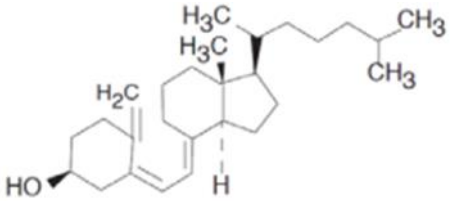
Calcitriol

Subchronic reported toxicity studies in rats and dogs indicated that calcitriol at an oral dose of 20 ng/kg/day (twice the usual human dosage) for up to 6 months produced no or minimal adverse effects. A dose of 80 ng/kg/day (8 times the usual human dosage) for up to 6 months Page 12 of 18 produced moderate adverse effects; changes seen appeared to be primarily the result of prolonged hypercalcemia. Reproductive toxicity reported studies in rats indicated that oral doses up to 300 ng/kg/day (30 times the usual human dose) did not adversely affect reproduction. In rabbits, multiple foetal abnormalities were observed in two litters at an oral maternally toxic dose of 300 ng/kg/day and one litter at 80 ng/kg/day, but not at 20 ng/kg/day (twice the usual human dose). Although there were no statistically significant differences between treated groups and controls in the numbers of litters or foetuses showing abnormalities, the possibility that these findings were due to calcitriol administration could not be discounted.

7. Description

Vitamin D3 (Cholecalciferol)

Cholecalciferol is the naturally occurring form of Vitamin D3. It is produced from 7-dehydro cholesterol, a sterol presents in mammalian skin, by ultraviolet irradiation. Its empirical formula is $C_{27}H_{44}O$, and molecular weight is 384.6. It is chemically as (5Z,7E) -(3S)-9,10-secocholesta5,7,10(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.

Shelcal CT

Shelcal CT is white coloured, Pearlescent, capsule shaped, biconvex film coated tablet with plain surface on both sides.

The excipients used are Gelatin, Sodium Methyl Paraben, Propyl Paraben Sodium, Crospovidone, Talc, Starch, Microcrystalline Cellulose, Butylated Hydroxy Anisole, Butylated Hydroxy Toluene, magnesium Stearate, Instacoat Aqua, Instacoat Smart.

8. Pharmaceutical particulars

8.1. Incompatibilities

Not applicable

8.2. Shelf-life

Do not use later than date of expiry.

8.3. Packaging information

Shelcal CT is available in pack of 15 tablets.

8.4. Storage and handing instructions.

Store in a Cool, Dry Place. Protect from Light.

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

Manufactured by:

Pure and Cure Healthcare Pvt. Ltd.

Plot No.: 26A-30, Sector -8A, IIE, SIDCUL,

Ranipur, Haridwar-249403, Uttarakhand.

11. Details of permission or licence number with date

Mfg Lic No. 51/UA/SC/P-2013 issued on 02.01.2023.

12. Date of revision

NA

MARKETED BY

TORRENT PHARMACEUTICALS LTD.

IN/ SHELCAL CT /Sep-25/01/PI