
SHELCAL SYRUP

1. Generic Name

Suspension of Calcium with Vitamin D₃.

2. Qualitative and quantitative Composition:

Each 5ml of the suspension contains:

625mg Calcium Carbonate from an organic source

(Powdered Oyster Shell) equivalent to

Elemental Calcium 250 mg

Vitamin D3 I.P. 125 IU

Flavoured Syrup Base q.s.

Colour: Erythrosine

Appropriate Overages of Vitamins added to compensate for loss on storage.

The list of excipients used are Sucrose, Methyl Paraben, Propyl Paraben, Xanthan Gum, Propylene Glycol, Erythrosine Supra.

3. Dosage form and strength

Dosage form: Syrup

Strength: 250 mg + 125 IU

4. Clinical particulars

4.1 Therapeutic indication

It is indicated in calcium deficiency, supplementation of calcium during growth, pregnancy, lactation or as recommended by the Physician.

4.2 Posology and method of administration

As directed by the physician.

4.3 Contraindications

Diseases and/or conditions resulting in hypercalcaemia and/or hypercalciuria (e.g. myeloma, bone metastases, primary hyperparathyroidism).

- Nephrolithiasis/nephrocalcinosis
- Renal failure
- Hypervitaminosis D
- Hypersensitivity to the active substances or to any of the excipients

4.4 Special warnings and precautions for use

During long-term treatment, serum and urinary calcium levels should be followed and renal function should be monitored through measurements of serum creatinine. Monitoring is especially important in elderly patients on concomitant treatment with cardiac glycosides or diuretics and in patients with a high tendency to calculus formation. In case of hypercalcaemia or signs of impaired renal function the dose should be reduced or the treatment discontinued.

Patients with mild to moderate impairment of renal function should be supervised carefully and the effect on calcium and phosphate levels should be monitored. The risk of soft tissue calcification should be taken into account. In patients with severe renal insufficiency, vitamin D in the form of colecalciferol is not metabolised normally and other forms of vitamin D should be used.

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

Calcium and Vitamin D3 should be prescribed with caution to patients suffering from sarcoidosis, due to the risk of increased metabolism of vitamin D into its active form. These patients should be monitored with regard to the calcium content in serum and urine.

Calcium and Vitamin D3 should be used with caution in immobilised patients with osteoporosis due to increased risk of hypercalcaemia.

Calcium and Vitamin D3 should be used with caution in other patients with increased risk of hypercalcaemia e.g. those suffering from malignancies.

The content of vitamin D (125/250 IU) in Shelcal should be considered when prescribing other medicinal products containing vitamin D. Additional doses of calcium or vitamin D should be taken under close medical supervision. In such cases it is necessary to monitor serum calcium levels and urinary calcium excretion frequently.

Caution should be exercised while prescribing Cholecalciferol and other medicinal products containing Vitamin D3 or nutrients (such as milk). Additional doses of calcium or Vitamin D3 increase the risk of hypercalcaemia with subsequent kidney function impairment and milk-alkali syndrome; therefore they should be taken under close medical supervision. In such cases it is necessary to monitor serum calcium levels and urinary calcium excretion frequently.

4.5 Drugs interactions

Thiazide diuretics reduce the urinary excretion of calcium. Due to increased risk of hypercalcaemia, serum calcium should be regularly monitored during concomitant use of thiazide diuretics. Hypercalcaemia must be avoided in digitalised patients.

Systemic corticosteroids reduce calcium absorption. During concomitant use, it may be necessary to increase the dose of Calcium and Vitamin D3.

Simultaneous treatment with ion exchange resins such as cholestyramine or laxatives such as paraffin oil may reduce the gastrointestinal absorption of vitamin D.

Calcium carbonate may interfere with the absorption of concomitantly administered tetracycline preparations. For this reason, tetracycline preparations should be administered at least two hours before or four to six hours after oral intake of calcium.

Hypercalcaemia may increase the toxicity of cardiac glycosides during treatment with calcium and vitamin D. Patients should be monitored with regard to electrocardiogram (ECG) and serum calcium levels.

If a bisphosphonate or sodium fluoride is used concomitantly with Calcium and Vitamin D3, these medicinal products should be administered at least three hours before the intake of Calcium and Vitamin D3 since gastrointestinal absorption may be reduced.

Rifampicin, phenytoin or barbiturates may reduce the activity of vitamin D3, since they increase the rate of its metabolism.

Calcium salts may decrease the absorption of iron, zinc or strontium. Consequently, the iron, zinc or strontium preparation should be taken at a distance of two hours from the calcium preparation.

Calcium salts may reduce the absorption of the estramustin or thyroid hormones. It is recommended that taking Calcium and Vitamin D3 be spaced at least 2 hours from these medicines.

Oxalic acid (found in spinach, sorrel and rhubarb) and phytic acid (found in whole cereals) may inhibit calcium absorption through formation of insoluble compounds with calcium ions. The patient should not take calcium products within two hours of eating foods high in oxalic acid and phytic acid.

The efficacy of levothyroxine can be reduced by the concurrent use of calcium, due to decreased levothyroxine absorption. Administration of calcium and levothyroxine should be separated by at least four hours. The absorption of quinolone antibiotics may be impaired if administered concomitantly with calcium. Quinolone antibiotics should be taken two hours before or after intake of calcium.

4.6 Use in special populations (such as pregnant and lactating women etc.)

Pregnancy

Calcium and Vitamin D3 may be given during pregnancy in cases of calcium and vitamin D3 deficiency.

During pregnancy the daily dose should not exceed 1500 mg of calcium and 600 IU of vitamin D. Animal studies have shown toxic effects on reproduction at high doses of vitamin D. In pregnant women, all calcium or vitamin D overdoses must be avoided as prolonged hypercalcaemia in pregnancy may lead to retardation of physical and mental development, supraaortic stenosis and retinopathy in the child. There are no indications that Vitamin D3 at therapeutic doses is teratogenic in human.

Breast-feeding

Calcium and Vitamin D3 can be used during breast-feeding. Calcium and vitamin D pass into breast milk. This should be considered when giving additional vitamin D to the child.

4.7 Effects on ability to drive and use machines

Shelcal Syrup has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Adverse reactions are listed below, by system organ class and frequency. Frequencies are defined as: uncommon (>1/1,000 to <1/100) or rare (>1/10,000 to <1/1,000).

Metabolism and nutrition disorders

Uncommon: Hypercalcaemia and hypercalciuria.

Gastrointestinal disorders

Rare: Constipation, 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.

4.9 Overdose

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, renal calculi 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.

Treatment of hypercalcaemia: The treatment with calcium and vitamin D must be discontinued. Treatment with thiazide diuretics, lithium, vitamin A, vitamin D and cardiac glycosides must also be discontinued. Gastric lavage in patients with impaired consciousness. Rehydration, and, according to severity, isolated or combined treatment with loop diuretics, bisphosphonates, calcitonin and corticosteroids. Serum electrolytes, renal function and diuresis must be monitored. In severe cases, ECG and CVP should be followed.

5 Pharmacological properties

5.1 Pharmacodynamics properties

Vitamin D3

Vitamin D3 increases the intestinal absorption of calcium. Administration of calcium and Vitamin D3 counteracts the increase of parathyroid hormone (PTH) which is caused by calcium deficiency and which causes increased bone resorption.

5.2 Pharmacokinetics properties

Vitamin D

Absorption: Vitamin D3 is absorbed in the small intestine.

Distribution and metabolism:

Colecalciferol and its metabolites circulate in the blood bound to a specific globulin. Colecalciferol is converted in the liver by hydroxylation to the active form 25-hydroxy colecalciferol. It is then further converted in the kidneys to 1,25 hydroxy colecalciferol. 1, 25 hydroxycalciferol is the metabolite responsible for increasing calcium absorption. Vitamin D which is not metabolised is stored in adipose and muscle tissues.

Elimination:

Vitamin D is excreted in faeces and urine.

Calcium**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 bloodcalcium 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:

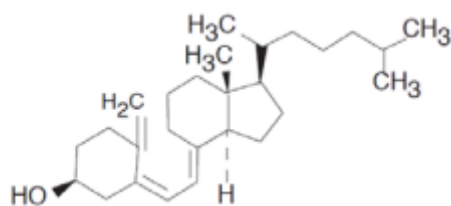
Calcium is eliminated through faeces, urine and sweat. Renal excretion depends on glomerular filtration and calcium tubular reabsorption.

6 Nonclinical properties**6.1 Animal Toxicology or Pharmacology**

There is no available data

7 Description**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:

**Calcium**

Calcium is a mineral that is present naturally in the food. Calcium is an element with atomic symbol Ca, atomic number 20, and atomic weight 40.08.

Shelcal Syrup

Shelcal Syrup is Pink Coloured easily redispersible suspension with pleasant flavour. The list of excipients used are Sucrose, Methyl Paraben, Propyl Paraben, Xanthan Gum, Propylene Glycol, Erythrosine Supra.

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 Syrup is available in bottle pack of 200 ml.

8.4 Storage and handing instructions

Store in a cool place. Protect from light.

Keep out of reach of Children.

Shake well before use.

Keep the bottle tightly closed after every use.

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

Akums Drugs & Pharmaceuticals Ltd.

Plot No. :22, Sector-6A, I.I.E, SIDCUL,

Ranipur, Haridwar-249 403, (Uttarakhand).

11 Details of permission or licence number with date

Mfg. Lic. No. is 129/UA/SC/P-2007, issue on 04.01.2023

12. Date of revision

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