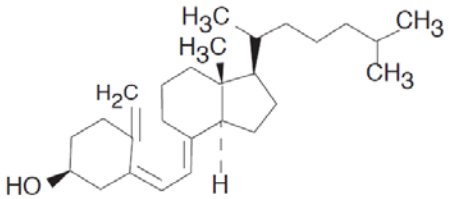
**For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory**

# SHELCAL SYRUP
# (SUSPENSION OF CALCIUM WITH VITAMIN $D_3$ 200ml)

## COMPOSITION
### SHELCAL SYRUP
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 Syrupy Base …… q.s.
Colour: Erythrosine
Appropriate overages of vitamins added to compensate for loss on storage

## DESCRIPTION
### 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.

## CLINICAL PHARMACOLOGY
### PHARMACODYNAMIC
**Vitamin $D_3$**
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.

### PHARMACOKINETIC
**Vitamin D**
**Absorption:** Vitamin $D_3$ 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 hydroxycolecalciferol 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 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.

## INDICATION
In calcium deficiency, supplementation of calcium during growth, pregnancy, lactation or as recommended by the Physician.

## DOSAGES AND ADMINISTRATION
As directed by the physician.

## 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

## WARNING AND PRECAUTION
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 exretion should be measured to exclude hypercalciuria.

Calcium and Vitamin $D_3$ 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 $D_3$ should be used with caution in immobilised patients with osteoporosis due to increased risk of hypercalcaemia.

Calcium and Vitamin $D_3$ 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 $D_3$ 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.

**DRUG INTERACTION**

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 $D_3$.

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 $D_3$, these medicinal products should be administered at least three hours before the intake of Calcium and Vitamin $D_3$ since gastrointestinal absorption may be reduced.

Rifampicin, phenytoin or barbiturates may reduce the activity of vitamin $D_3$, 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 $D_3$ 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.

## USE IN SPECIFIC POPULATION

### Pregnancy

Calcium and Vitamin $D_3$ may be given during pregnancy in cases of calcium and vitamin $D_3$ 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, supravalvular aortic stenosis and retinopathy in the child. There are no indications that Vitamin $D_3$ at therapeutic doses is teratogenic in human.

**Breast-feeding**
Calcium and Vitamin $D_3$ 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.

**ADVERSE REACTION**
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.

**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.

**SHAKE WELL BEFORE USE**

**Keep out of reach of children**

**EXPIRY DATE**
Do not use later than the date of expiry.

**STORAGE**
Store in a cool and dry place
Protect from light

**PRESENTATIONS**
Shelcal Syrup is available in bottle pack of 200ml

**MARKETED BY:**
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