

Oshecad™

Elemental Calcium 500 mg and Vitamin D3 250 I.U. Tablets

The Oyster Shell Calcium with Vitamin D

Product Description:

Each film coated tablet contains:

1.25 g of calcium carbonate I.P. from an organic source (Oyster shell)

- eq. to elemental calcium 500 mg
- Vitamin D3 250 I.U.

General Information

Patients with chronic kidney disease-mineral bone disorder (CKD-MBD) have altered mineral metabolism due to disruptions in homeostasis of serum calcium, phosphate, and the mineral-regulating hormones, parathyroid hormone (PTH), 1,25-dihydroxyvitamin D₃(1,25(OH)₂D), and fibroblast growth factor-23 (FGF-23). Progressive hypocalcemia and hyperphosphatemia as kidney function decreased were the original biochemical hallmarks of mineral bone disorder. Calcium and phosphorus absorption studies showed that intestinal calcium and phosphorus absorption were low in CKD and reversible with vitamin D analogs.

Hypocalcemia from calcium malabsorption and hyperphosphatemia from phosphorus retention, were considered to be responsible for the progression of secondary hyperparathyroidism, a common feature of CKD.

Calcium is the most abundant mineral in the body. Around 99% of total body calcium is stored in the bones and teeth, where it is essential for growth and maintenance. Around 1% is found in the blood, muscle, and cell fluids where it is needed for muscle contraction, heart contraction, blood clotting, secretion of hormones and enzymes, and sending messages through the nervous system.

Calcium carbonate is a popular phosphate binder as it binds dietary phosphate when given with meals. It also has the added advantage of preventing or reversing negative skeletal calcium balance which is thought to contribute to the increased fracture risk in CKD.

Vitamin D helps your body absorb calcium and phosphorus. Having the right amounts of vitamin D, calcium, and phosphorus is important for building and keeping strong bones.

Oshecad tablet is used to treat conditions caused by low calcium levels such as bone loss (osteoporosis), weak bones (osteomalacia/rickets), decreased activity of the parathyroid gland (hypoparathyroidism), and a certain muscle disease (latent tetany).

Indication & Usage

Oshecad tablet is used for symptom relief in:

- In the treatment of calcium deficiency state which may occur in diseases such as hypoparathyroidism (acute and chronic)
- A phosphate binder in patients with chronic renal failure
- As a dietary supplement where calcium intake may be inadequate: during childhood, adolescence, pregnancy, lactation, in postmenopausal women and the aged.

Dosage and Administration

Phosphate binding in renal impairment

1 tablet TID along with meal (dailyintake of calcium should not be > 2500 mg /day)

Daily dietary supplement

1 tablet BID with or without food(food may increase absorption)

Renal impairment

In patients with moderate to severe renal impairment there is an increased risk of hypercalcemia and calcium carbonate should be used cautiously in these patients.

Mechanism of action

Calcium plays a vital role in the anatomy, physiology and biochemistry of organisms and of the cell, particularly in signal transduction pathways. The skeleton acts as a major mineral storage site for the element and releases Ca²⁺ ions into the bloodstream under controlled conditions. Circulating calcium is either in the free, ionized form or bound to blood proteins such as serum albumin. Parathyroid hormone (secreted from the parathyroid gland) regulates the resorption of Ca²⁺ from bone. Calcitonin stimulates incorporation of calcium in bone, although this process is largely independent of calcitonin.

Pharmacokinetic

Calcium

Absorption:

Maximal absorption occurs at doses of 500 mg or less taken with food. Oral bioavailability depends on intestinal pH, the presence of food and dosage.

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 D

Absorption:

Vitamin D3 is absorbed in the small intestine.

Distribution and metabolism:

Cholecalciferol and its metabolites circulate in the blood bound to a specific globulin. Cholecalciferol is converted in the liver by hydroxylation to the active form 25-hydroxycholecalciferol. It is then further converted in the kidneys to 1,25 di-hydroxycholecalciferol. 1,25 di-hydroxycholecalciferol 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.

Use in Specific Population

Pregnancy: It is unknown whether using Oshecad during pregnancy will harm the foetus. Tell your doctor if you are pregnant or planning to become pregnant. Your doctor will weigh the potential benefits and risks of Oshecad before prescribing it to you.

Nursing Mother: It is unknown whether using Oshecad while breastfeeding will harm the breastfed infant. Tell your doctor if you are breastfeeding or planning to breastfeed. Your doctor will weigh the potential benefits and risks of Oshecad before prescribing it to you.

Contraindication: Oshecad should not be used under below mentioned conditions.

- Allergy to calcium carbonate or any other components of the product;
- Hypercalcaemia;
- Severe hypercalciuria.

Warning & Precaution:

Special care needs to be taken when using Oshecad under below mentioned conditions.

- Mild hypercalciuria;
- Impaired kidney function;
- Kidney stones.

Drug Interaction:

Calcium may affect the effectiveness of some medications, particularly:

- Antibiotics, especially fluoroquinolones and tetracyclines;
- Levothyroxine (thyroid hormone replacement).

Adverse Reactions:

- Metabolism and nutrition disorders
- Hypercalcaemia and hypercalciuria.
- Gastrointestinal disorders like constipation, flatulence, nausea, abdominal pain

