Calcium with Vitamin D3
Gemcal D3

1. NAME OF THE MEDICINAL PRODUCT

Calcium with Vitamin D_3 capsule

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each soft gelatin capsule contains
Calcium Carbonate I.P.……1250 mg
(equivalent to elemental Calcium 500 mg)
Vitamin D3 I.P……...500 IU
Excipients……..q.s.
Approved colours used in capsule shell.
Appropriate overage of Vitamin is added to compensate loss on storage

3. PHARMACEUTICAL FORM

Soft gelatin capsule

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

To be used during calcium deficiency, supplementation of calcium during growth, pregnancy, lactation or as directed by the Physician. It may be used as an adjunct to specific therapy for the osteoporosis.

4.2 Posology and Method of Administration

As directed by physician.

Oral
Adjunctive therapy in osteoporosis
One tablet 2-3 times per day

Calcium and Vitamin D3 deficiency
Adults: One tablet 2-3 times per day
Children: One tablet 1-2 times per day

Adults and the elderly

One tablet twice a day (e.g. one tablet in the morning and one tablet in the evening). Dose reduction should be considered as necessary following the monitoring of calcium levels.

Pregnancy:
During pregnancy the daily intake should not exceed 1500 mg calcium and 600 IU Vitamin D3. However, Endocrine Practice Guidelines Committee recommends 1,500–2,000 IU vitamin D3 daily for pregnant at risk for vitamin D deficiency. Studies in animals have shown reproductive toxicity with high doses of Vitamin D3. In pregnant women, overdoses of calcium and Vitamin D3 should be avoided as permanent hypercalcaemia has been related to adverse effects on the developing foetus. There are no indications that Vitamin D3 at therapeutic doses is teratogenic in humans. Calcium and Vitamin D3 tablets can be used during pregnancy, in case of a calcium and Vitamin D3 deficiency.

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

Dose Modification
Safety and tolerability
Dosage in hepatic impairment: No dose adjustment is required.
Dosage in renal impairment: Should not be used in patients with severe renal impairment.

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 Special Precautions for Use

The risk–benefit ratio should be considered when the following medical problems exist:
• Cholecalciferol should be used with caution in patients with renal impairment 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 impairment, vitamin D in the form of cholecalciferol is not metabolized normally and another form of vitamin D should be used.

• During long-term treatment, serum and urinary calcium levels should be measured and renal function should be monitored through the measurement 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. Treatment must be reduced or suspended if urinary calcium exceeds 7.5 mmol/24 hours (300 mg/24 hours). In case of hypercalcaemia or signs of impaired renal function, treatment with cholecalciferol should be discontinued. Chronic or acute administration of excessive doses may lead to hypervitaminosis D, manifested by hypercalcaemia and its sequelae.

• Vitamin D should be used with caution in patients with impairment of renal function 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, cholecalciferol is not metabolized normally and other forms of vitamin D should be used.

• The dose of cholecalciferol should be considered when prescribing other drugs 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.

• Cholecalciferol should be used with caution in patients suffering from sarcoidosis because of the risk of increased metabolism of vitamin D to its active metabolite. In these patients, serum calcium levels and urinary calcium excretion must be monitored.

• Cholecalciferol should be used with caution in immobilized patients with osteoporosis due to the increased risk of hypercalcaemia. The cholecalciferol treatment should be discontinued in prolonged immobilization and should only be resumed once the patient becomes mobile again.

• Conditions such as arteriosclerosis or cardiac function impairment may be exacerbated due to the possibility of hypercalcaemia and elevated serum cholesterol concentrations.

• Cholecalciferol should be administered with caution in patients with hyperlipidaemia as it could potentially exacerbate low-density lipoprotein (LDL) elevation. Administration of cholecalciferol in patients with hyperphosphataemia may put the patient at risk of metastatic calcification; normalization of phosphate levels are indicated prior to therapy. Liver disease may, in turn, impair the absorption of cholecalciferol

4.5 Interaction with Other Medicinal Products and Other Forms of 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 D3 Tablets.

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 Tablets, these medicinal products should be administered at least three hours before the intake of Calcium and Vitamin D3 Tablets 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 Tablets 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 Fertility, Pregnancy and Lactation

Fertility

Vitamin D and 1,25-dihydroxycholecalciferol seemed to influence male fertility by acting on classic target tissues and regulating levels of calcium in reproductive tissues.

Pregnancy:

Studies in animals have shown reproductive toxicity with high doses of Vitamin D3. In pregnant women, overdoses of calcium and Vitamin D3 should be avoided as permanent hypercalcaemia has been related to adverse effects on the developing foetus. There are no indications that Vitamin D3 at therapeutic doses is teratogenic in humans. Calcium and Vitamin D3 tablets can be used during pregnancy, in case of a calcium and Vitamin D3 deficiency.

Lactation:

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

4.7 Effects on Ability to Drive and Use Machines

Calcium and vitamin D3 do not seem to show any effect on the ability to drive and use machines.

4.8 Undesirable Effects

Table 1. Adverse Reactions Reported in Clinical Trials

System organ class	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

4.9 Overdose

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

Clinical Studies

5.2 Pharmacokinetic Properties

5.3 Preclinical Safety Data

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

6.2 Incompatibilities

6.3 Shelf-life

6.4 Special Precautions for Storage

6.5 Nature and Contents of Container

6.6 Special Precautions for Disposal

Manufactured & Marketed By: Details