Prescribing information (Summary of Product Characteristics)

1. Name of the Medicinal Product

Brand Name: ZECAL –D_3

Generic Name: CALCIUM and Vitamin D_3 Capsules

2.Qualitative and Quantitative Composition

Each Soft gelatin capsule contains:

Calcium Carbonate BP……. 1250 mg

(Equivalent to elemental Calcium 500 mg)

Vitamin D3 BP ……..…….. 500 IU

3.Pharmaceutical Form

Solid Capsules

Description: A white and pink coloured, opaque, oval shaped soft gelatin capsule containing off white oily paste

4.Clinical Particulars

4.1 Therapeutic Indications

Calcium plays a very important role in the body. It is necessary for normal functioning of nerves, cells, muscle and bone. If calcium in blood is deficient, then the body removes calcium from bones, thereby weakening bones. Prolonged bone resorption from chronic dietary deficiency results in osteoporosis either by inadequate accumulation of bone mass during growth or increased rate of bone loss at menopause.

Vitamin D3 is fat-soluble sterol essential for the proper regulation of calcium and phosphate homeostasis and bone mineralization.

As an adjunct to specific therapy for osteoporosis and in situations requiring therapeutic supplementation such as in pregnancy and established Vitamin D dependent osteomalacia. Prevention and treatment of Calcium deficiency/Vitamin D deficiency especially in elderly subjects.

4.2 Posology and Method of Administration

The usual recommended dose is 1 to 2 capsules daily, do not exceed recommended dose. And as prescribed by the physician.

Oral administration

4.3 Contraindications

Hypercalcaemia, Osteoporosis due to prolong immobilization, renal stones and severe
hypercalciuria.

4.4 Special Warnings and Special Precautions for Use

Patients with mild to moderate renal failure or mild hypercalcuria should be supervised carefully including periodic checks of plasma calcium and urinary excretion In patients with a history of renal stones urinary calcium excretion should be measured to exclude hypercalcuria.

Caution is required in patients receiving treatment for cardiovascular disease with thiazide diuretics or cardiac glycosides including digitalis.

Allowance should be made for calcium with vitamin D supplements from other sources.

Caution should be exercised in pregnancy and lactation.

4.5 Interaction with other Medicinal Products and other forms of Interaction

The risk of hypercalcaemia should be considered in patients taking thiazide diuretics since these drugs can reduce urinary calcium excretion.

Certain foods (e.g. those containing oxalic acid, phosphate or phytinic acid) may reduce the absorption of calcium.

Concomitant treatment with phenytoin or barbiturates can decrease the effect of vitamin D because of metabolic activation. Concomitant use of glucocorticoids can decrease the effect of Vitamin D.

The effect of digitalis and other cardiac glycosides may be accentuated with the oral administration of calcium combined with vitamin D.

Calcium salts may reduce the absorption of thyroxine, bisphosphonates, sodium fluoride, Quinolones, tertacycline and iron. It is advisable to allow a minimum period of four hours before taking calcium preparations.

4.6 Pregnancy and Lactation

Consult your healthcare professional before use if you are pregnant or breast feeding.

4.7 Undesirable effects:

The use of calcium supplements has rarely, given rise to mild gastro-instestinal disturbances, such as constipation, flatulence, nausea, gastric pain, diarrohea.

Following administration of Vitamin D supplements occasional skin rash has been reported, Hypercalcuria, and in rare cases hypercalcaemia have been seen with long term treatment at high dosages.

4.8 Overdose and treatment:

The use of calcium supplements has rarely, given rise to mild gastro-instestinal disturbances, such as constipation, flatulence, nausea, gastric pain, diarrohea. Following administration of Vitamin D supplements occasional skin rash has been reported, hypercalcuria , and in rare cases hypercalcaemia have been seen with long term treatment at high dosages.

4.9 Overdose

Overdose can lead to hypervitaminosis 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.

Milk-alkali syndrome may occur in patients who ingest large amounts of calcium and absorbable alkali. Symptoms are frequent urge to urinate, continuing headache, continuing loss of appetite, nausea or vomiting, unusual tiredness or weakness, hypercalcaemia, alkalosis and renal impairment.

5.Pharmacological Properties

5.1 Pharmacodynamic properties:

Pharmacotherapeutic group: Calcium, combination with vitamin D and/or other drugs
ATC code: A12AX
Vitamin D increases the intestinal absorption of calcium.
Administration of calcium and vitamin D3 (colecalciferol) counteracts the increase of parathyroid hormone (PTH), which is caused by calcium deficiency and which causes
increased bone resorption.

A clinical study of institutionalized patients suffering from vitamin D deficiency indicated that a daily intake of two capsules of calcium 500 mg/Vitamin D 400 IU for six months normalised the value of the 25-hydroxylated metabolite of Vitamin D3 and reduced secondary hyperparathyroidism and alkaline phosphatases.

An 18-month double blind, placebo controlled study including 3270 institutionalized women aged 84±6 years that received supplementation of vitamin D (800 IU/day) and calcium phosphate (corresponding to 1200 mg/day of elemental calcium), showed a significant decrease of PTH secretion. After 18 month, an “intent-to treat” analysis showed 80 hip fractures in the calcium-vitamin D group and 110 hip fractures in the placebo group (p=0.004). A follow-up study after 36 months showed 137 women with at least one hip fracture in the calcium-vitamin D group (n=1176) and 178 in the placebo group (n=1127, p<0.02).

5.2 Pharmacokinetic properties:

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 ionized 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 feces, 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:

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-hydroxycholecalciferol. It is then further converted in the kidneys to 1,25 hydroxycholecalciferol. 1,25 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 feces and urine.

6.Pharmaceutical Particulars

6.1 List of Excipients

Butylated Hydroxyanisole	BP
Butylated Hydroxytoluene	BP
Soya lecithin	USP
Refined Soyabean Oil	USP

6.2 Incompatibilities

Not applicable

6.3 Shelf Life

24 Months

6.4 Special Precautions for Storage

Store in a dry place below 30^0C. Do not freeze.

6.5 Nature and contents of container:

3 blisters of 10 capsules

6.6 Special precautions for disposal and other handling

No special requirements

7. Marketing authorisation holder

Indchemie Health Specialities Pvt. Ltd.

Plot No. 7, OIDC, Mahatma Gandhi Udyog Nagar,

Dabhel, Daman, -396210

8.Marketing authorisation number

TAN 22 HM 0337

9.Date of first authorisation/renewal of the authorisation

21/09/2022

10.Date of revision of the text