



**Flavoured chewable tablets**

(Calcium Citrate 1000 mg, Magnesium Hydroxide 100 mg, Vitamin D3 200 IU, Zinc 4 mg)

**Composition:**

Each Uncoated tablet Contains:

Calcium citrate U.S.P ..... 1000 mg

Magnesium hydroxide IP

Eq. to elemental Magnesium.... 100 mg

Vitamin D<sub>3</sub> I.P ..... 200 IU

Zinc Sulphate monohydrate I.P.

Eq. to elemental Zinc..... 4 mg

Excipients... .....q.s.

**Clinical Pharmacology**

**Calcium Citrate:**

Calcium citrate increases plasma calcium levels and reduces calcium flux from osteocyte activity by reducing the secretion of parathyroid hormone (PTH). Calcium stimulates G-protein coupled calcium receptor on the surface of parathyroid cells. The reduction in calcium flux increases the amount of calcium deposited in bone resulting in an increase in bone mineral density. The reduction in PTH secretion also reduces the amount of vitamin D metabolized to its active form, calcidiol. Since calcidiol increases the expression of calcium dependent ATPases and transient receptor potential cation channel subfamily V member 6 (TRPV6) both of which are involved in calcium uptake

from the gut, a reduction in calcidiol results in less calcium absorption. Additionally, TRPV5, the channel responsible for calcium reabsorption in the kidney, is down regulated when PTH secretion is reduced thus increasing calcium excretion via the kidneys. Another hormone, calcitonin, is likely involved in the reduction of bone reabsorption during periods of high plasma calcium.

### **Vitamin D3:**

Vitamin D is hydroxylated in the liver to form 25-hydroxycholecalciferol and then undergoes further hydroxylation in the kidney to form the active metabolite 1, 25 dihydroxycholecalciferol (calcitriol). In its biologically active form vitamin D3 stimulates intestinal calcium absorption, incorporation of calcium into the osteoid and release of calcium from bone tissue. In the small intestine it promotes rapid and delayed calcium uptake. The passive and active transport of phosphate is also stimulated. In the kidney, it inhibits the excretion of calcium and phosphate by promoting tubular resorption. The production of parathyroid hormone (PTH) in the parathyroid is inhibited directly by the biologically active form of vitamin D3. PTH secretion is inhibited additionally by the increased calcium uptake in the small intestine under the influence of biologically active vitamin D3.

### **Zinc:**

Zinc is involved in various aspects of cellular metabolism. It has been estimated that approximately 10% of human proteins may bind zinc, in addition to hundreds of proteins that transport and traffic zinc. It is required for the catalytic activity of more than 200 enzymes, and it plays a role in immune function wound healing, protein synthesis, DNA synthesis, and cell division. Zinc is absorbed in the small intestine by a carrier-mediated mechanism. Zinc particles were mainly distributed to organs including the liver, lung, and kidney. Zinc is released from food as free ions during its digestion. These freed ions may then combine with endogenously secreted ligands before their transport into the enterocytes in the duodenum and jejunum. The excretion of zinc

through gastrointestinal tract accounts for approximately one-half of all zinc eliminated from the body.

### **Magnesium Hydroxide:**

Magnesium hydroxide is an antacid react with HCl in stomach to form magnesium chloride & water. It decreases the direct acid irritant effect and increases the pH in the stomach leading to inactivation of pepsin. Magnesium hydroxide enhances the integrity of the mucosal barrier of the stomach as well as improving the tone of both the gastric and esophageal sphincters. Magnesium hydroxide is absorbed very slowly through the small intestine & excreted in the urine through the kidneys.

### **Indications:**

SMICAL tablet used clinically is usually prescribed as dietary supplement, Prevention and treatment of vitamin D deficiency states. Hypocalcemic seizures, rickets, chronic illnesses, In case of Loss of sense of smell and taste, Weight loss, Pale skin, Diarrhea, White spots under finger nails, constipation condition.

### **Use in special population**

#### **Pregnancy:**

Calcium intake is important during pregnancy because of the potential adverse effect on maternal bone health if maternal calcium stores are depleted. Calcium supplementation during pregnancy reduces the prevalence of pre-eclampsia. Reduction in the composite outcome of maternal death or serious morbidity with calcium supplementation. Calcium supplementation in the second half of pregnancy reduces blood pressure.

#### **Lactation:**

Calcium intake is important during lactation because of the potential adverse effect on maternal bone health if maternal calcium stores are depleted.

### **Postmenopausal Osteoporosis:**

Continuous treatment of postmenopausal osteoporosis with calcium for three years is safe and significantly reduces the rate of new vertebral fractures in women with this disorder.

### **Precautions and Warnings:**

Hypercalcemia/hypervitaminosis difficulty absorbing nutrition from food calcium not uses.

### **Drug Interactions:**

SMICAL tablet contraindicate with tetracycline antibiotics, quinolone antibiotics, Cisplatin, penicillamine, dasatinib, delavirdine, atazanavir, gabapentin, digoxin, mycophenolate, phosphate supplements, tetracycline antibiotics, certain azole antifungal and quinolone antibiotics.

### **Adverse effects:**

High dose of SMICAL tablet can cause weakness, fatigue, and sleepiness, and headache, loss of appetite, dry mouth, metallic taste, nausea and vomiting.

### **Overdosage:**

Long term use of SMICAL tablet causes nausea & vomiting, Stomach pain & Diarrhea, Flu like symptoms, low good HDL cholesterol, Change in taste, Copper Deficiency, Frequent infections, slow/irregular heartbeat.

### **Contraindications:**

Hypersensitivity to cholecalciferol, ergocalciferol, or vitamin D metabolites (eg calcitriol, calcifediol, alfacalcidol, calcipotriol). Hypercalcemia (exacerbation with enhanced

toxicity) Hypervitaminosis D (worsening of condition, pretherapy 25-hydroxycholecalciferol levels should be considered in selected patients)

**Precautions and Warnings:**

SMICAL tablet should be used with caution in patients with impairment of renal function and the effects on calcium and phosphate levels should be monitored, the risk of soft tissue calcification should be taken into account. In patients with several renal insufficiency. In allergic conditions, In Kidney diseases, appendicitis or symptoms of appendicitis

**For Therapeutic use**

**Route of administration:** Oral

**Type of tablet:** Flavoured chewable tablet

**Flavour:** Lemon mint flavour

**Dosage:** As directed by the Physician

**Storage:** Store in a cool, dry & dark place.

**Presentation:** SMICAL Flavoured chewable tablets available as 10 X 10 Tablets.

**Marketed By:**



**EPIONE PHARMACEUTICALS PVT .LTD.**

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