

เอกสารกำกับยาภาษาอังกฤษ

(เหมือนกันทุกขนาดบรรจุ)

1. Name of the medicinal product

CALTAB-1000 mg tablet

CALTAB-835 mg tablet

2. Qualitative and quantitative composition

CALTAB-1000: Each tablet contains calcium carbonate 1000 mg eq. to Calcium 400 mg.

CALTAB-835: Each tablet contains calcium carbonate 835 mg eq. to Calcium 334 mg.

For the full list of excipients, see section 6.1.

3. Pharmaceutical Form

Tablet

CALTAB-1000: White, round, biconvex tablets, with engraved “CALTAB” on one side and plain on the other.

CALTAB-835: White, round, biconvex tablet with scored on one side and plain on the other.

4. Clinical Particulars

4.1 Therapeutic indications

- Prevention and treatment of hypocalcemia for patient with osteoporosis, postmenopausal, chronic renal failure and drug induce hypocalcemia.
- Prevention and treatment of calcium depletion.
- A dietary supplement when calcium intake may be inadequate for children, pregnancy, lactation, postmenopausal and in elderly patients.
- To sequester phosphate in the intestinal for patient with chronic renal failure.
- Antacid

4.2 Posology and method of administration

(1) Posology

Dosage in Adults:

- Prevention and treatment of hypocalcemia take 1 tablet 3 times daily after meals (recommended dose is about 1,000-1,200 mg daily)

- Treatment for calcium depletion take 2 tablet 2 times daily after meals (recommended dose is about 1,000-2,000 mg daily)
- Calcium supplement:
 - for 1-3 years take 1 tablet 1 time daily after meals (recommended dose 500 mg daily)
 - for 4-8 years take 1 tablet 2 time daily after meals (recommended dose 800 mg daily)
 - for 9-18 years take 1 tablet 2 time daily after meals (recommended dose 1,100 mg daily)
 - for 19-50 years take 1 tablet 2 time daily after meals (recommended dose 800 mg daily)
 - for 51 years or older take 1 tablet 2 time daily after meals (recommended dose 800-1,000 mg daily)
 - for pregnancy and lactation take 1 tablet 2 times daily after meals (recommended dose 800-1,000 mg daily)
- Sequester phosphate: the dose should be adjusted for the individual patient and is dependent on the serum phosphate level (maximum dose 2,000 mg daily)
- Antacid: take 2 tablet 2 times daily before meals (maximum dose 3,200 mg daily)

Dosage in special population

Dosage in Elderly patients:

Dosage as for adults.

Dosage in Pediatric patients:

Dosage as for adults.

Dosage in patients with impaired renal function:

Dosage adjustments may be necessary depending on the serum calcium levels in patient with CrCl < 25 mL/minutes.

Dosage in patients with impaired hepatic function:

No dose adjustment is required.

(2) Method of administration

Oral.

For phosphate binding, the tablets should be taken just before, during or just after each meal in order to bind phosphate in the food.

4.3 Contraindication

- Ventricular fibrillation,
- Hypercalcemia (associated with sarcoidosis, hyperparathyroidism, hypervitaminosis D, certain cancers)

4.4 Special warning and precautions for use

- Patients with renal disease
- GI Effects: Calcium salts also may cause constipation
- Hypercalcemia: Hypercalcemia is rarely produced by administration of calcium alone, but may occur when large doses are given to patients with chronic renal failure
- Renal Calculi: Because the principal constituents of most renal calculi (kidney stones) are calcium salts, a high dietary intake of calcium has long been suspected as contributing to the risk of renal calculi

4.5 Interactions with other medicinal products and other forms of interactions

- Bisphosphonates
Concomitant administration of calcium salts with bisphosphonates may reduce absorption of the bisphosphonate from the GI tract. To minimize this effect, calcium salts should be administered at separate times.
- Iron Preparations
Concomitant administration of calcium salts and oral iron preparations may result in reduced absorption of iron. Patients should be advised to take the drugs at different times, whenever possible.
- Levothyroxine
Calcium carbonate may form an insoluble chelate with levothyroxine, resulting in decreased levothyroxine absorption.
- Quinolones
Concomitant administration of calcium salts and some quinolones may reduce oral bioavailability of the quinolones.
- Tetracyclines
Calcium complexes tetracycline antibiotics rendering them inactive.

4.6 Pregnancy and lactation

Pregnancy

Available evidence is inconclusive or inadequate for determining fetal risk when used in pregnant women.

Nursing mothers

Available evidence and/or expert consensus is inconclusive or is inadequate for determining infant risk when used during breastfeeding. Weigh the potential benefits of drug treatment against potential risk before prescribing this drug during breastfeeding.

4.7 Effects on ability to drive and use machine

Calcium carbonate has no known influence on ability to drive and use machines.

4.8 Undesirable effects

- Cardiovascular Effect: Myocardial infarction
- Endocrine/Metabolic Effects: Hypercalcemia, mineral deficiency, neonatal hypocalcemia
- Gastrointestinal Effects: Constipation, flatulence, swollen abdomen
- Renal Effects: Hypercalciuria, renal impairment, urolithiasis
- Reproductive Effects: Prostate cancer
- Other: Milk alkali syndrome

4.9 Overdose

Overdosage may cause gastro-intestinal disturbances but would not be expected to cause hypercalcemia except in patients treated with excessive doses of vitamin D.

Treatment should be aimed at lowering serum calcium levels through a high fluid intake and low calcium diet. In severe cases treatments with corticosteroid and other specialist treatment may be necessary. Alkalosis is a potential but rare risk.

5. Pharmacological Properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Mineral supplements: Calcium.

ATC code: A12AA04

An adequate intake of calcium is of importance during growth, pregnancy and breastfeeding.

Calcium is essential for maintenance of the function integrity of nervous, muscular and skeletal systems and cell-membrane and capillary permeability. Calcium accounts for 1-2% of adults body weight, and more than 99% of total body calcium is found in bone and teeth. Calcium also is present in blood, extracellular fluid, muscle, and other tissues where it has roles in mediating vascular contraction and vasodilation, muscle contraction, nerve transmission and glandular secretion.

5.2 Pharmacokinetic properties

Absorption

Calcium is absorbed from the GI tract by active transport and passive diffusion. Calcium is actively absorbed in the duodenum and proximal jejunum. Calcium is never completely absorbed from the intestine. Calcium is absorbed in a soluble and ionized form. The efficiency of intestinal calcium absorption may be increased when calcium intake is reduced and during pregnancy and lactation when calcium requirements are higher than normal. Oral bioavailability of calcium from nonfood sources and supplements depends on intestinal pH, the presence or absence of a meal, and the dose. Calcium absorption is lower with a low protein diet than with a high protein diet.

Distribution and Biotransformation

Following absorption, calcium first enters the extracellular fluid and is then rapidly incorporated into skeletal tissue. Bone contains 99% of the body's calcium; the remaining 1% is distributed equally between the intracellular and extracellular fluids. Of the total serum calcium concentration, 50% is in the ionic form and 5% is complexed by phosphates, citrates, and other anions. Approximately 45% of the serum calcium is bound to plasma proteins; for a change in serum albumin of 1 g/dL, the serum calcium concentration may change about 0.8 mg/dL (0.04 mEq/dL).

Excretion and Elimination

Calcium is excreted mainly in the feces, consists of unabsorbed calcium and excreted by the sweat glands. Most of the calcium filtered by renal glomeruli is reabsorbed in the ascending limb of the loop of Henle and proximal and distal convoluted tubules. Urinary excretion of calcium decreases with reduction of ionic serum calcium concentrations but is proportionately increased as serum ionized calcium concentrations increase. Urinary excretion of calcium decreases during pregnancy, with aging and in the early stages of renal failure.

5.3 Preclinical safety data

There is no information of relevance to the safety assessment in addition to what is stated in other parts of the SmPC.

6. Pharmaceutical Particulars

6.1 List of excipients

Pregelatinized starch

Corn starch

Microcrystalline cellulose PH 301

Sodium lauryl sulphate

PEG 6000

Purified water*

Sodium starch glycolate

Magnesium stearate

* Evaporated during the manufacturing process.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years (Tentative shelf-life)

6.4 Special precautions for storage

Store below 30 °C.

6.5 Nature and contents of container

CALTAB-1000 : Tablets with packed in PVC-aluminium blister pack of 10 tablets packed/unpacked in catch cover of 1 pack and packed in paper box of 1, 5, 10, 12, 25, 50 and 100 packs.

CALTAB-835 : Tablets with packed in PVC-aluminium blister pack of 10 tablets/ HDPE plastic bottle of 60 and 100 tablet packed/unpacked in paper box of 1, 5, 10, 12, 25, 50 and 100 packs/bottle.

7. Manufacturer

Millimed Co., Ltd.

193 Moo 1, Suksawad Road, Pak Khlong Bang Plakot, Phra Samut Chedi, Samut Prakan
10290, Thailand.
Tel: +66 2461 1027

8. Marketing authorization number(s)

XXXXXXXX

9. Date of first authorization/renewal of the authorization

XX.XX.XX

10. Date of revision of the text

7 February 2023

Reference 1: CALTAB 1250 1A 410/65

Reference 1.1: Drug Information Handbook 2020-2021 29th edition

Reference 1.2: AHFS[®] Drug Information 2022

Reference 1.3: CALTAB-835 1A 15191/65

Reference 1.4: Dietary reference intake for THAIS 2020

Reference 1.5: Micromedex

Reference 1.6: Summary of Product Characteristics (SmPC) of Adcal 1500 mg chewable tablets, Date of revision July 2016, Available from URL: <https://www.medicines.org.uk/emc/product/1295/smpc>

Reference 1.7: CALTAB-835 1A 15193/65

Reference 4: Summary of Product Characteristics (SmPC) of Calcichew 500mg chewable tablets, Date of revision Feb 2022, Available from URL: <https://www.medicines.org.uk/emc/product/12847/smpc>