SUMMARY OF PRODUCT CHARACTERISTIC

1. Name of the medicinal product

Calcimore

2. Qualitative and quantitative composition

One chewable tablet contains 600 mg of calcium carbonate.
Excipients with known effect: sodium, sucrose.
For a full list of excipients, see section 6.1.

3. Pharmaceutical form

Chewable Tablets.
White biconvex tablets. One side engraved with 'Taro'. Other side plain.
Peppermint Odor.

4. Clinical particulars

4.1. Therapeutic indications

Antacid, calcium deficiency.

4.2. Posology and method of administration:

Posology

Antacid: 1-2 tablets as needed
Calcium deficiency: 2 tablets 1-3 times a day, 1-1.5 hours after meals.
Do not exceed the recommended dosage.
This medicine is not usually intended for administration to children under 6 years of age, unless recommended by a doctor.
For increased stomach acidity: If there is no improvement in your condition within 14 days, refer to your doctor.

Method of administration

Oral.
Tablets should be chewed.

4.3. Contraindications

- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
- Diseases and/or conditions resulting in hypercalcaemia and/or hypercalciuria, for example in hyperparathyroidism, vitamin D overdosage, decalcifying tumours such as plasmacytoma and skeletal metastases, in severe renal failure untreated by renal dialysis and in osteoporosis due to immobilisation.
- Renal calculi (nephrolithiasis)
- Patients on a low phosphate diet.
- Patients with Zollinger-Ellison Syndrome.
- Patients on cardiac glycosides

4.4. Special warnings and precautions for use

In renal insufficiency the tablets should be given only under controlled conditions for hyperphosphataemia. Caution should be exercised in patients with a history of renal calculi.
Monitoring is especially important in patients on concomitant treatment with or diuretics (see section 4.5).
During high dose therapy and especially during concomitant treatment with vitamin D and/or medications or nutrients (such as milk) containing calcium, there is a risk of hypercalcaemia and milk-alkali syndrome (hypercalcaemia, alkalosis and renal impairment) with subsequent kidney function impairment. In these patients, serum calcium levels should be monitored and renal function should be monitored.

Calcimore contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.
Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

4.5. Interaction with other medicinal products and other forms of interaction

Changes in gastric acidity, such as that caused by the ingestion of antacids, can affect the rate and degree to which some concurrently administered medicines are absorbed.

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. 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. Patients should be monitored with regard to electrocardiogram (ECG) and serum calcium levels.

If a bisphosphonate is used concomitantly, this preparation should be administered at least three hours before the intake of Calcimore since gastrointestinal absorption may be reduced.

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.

Calcium salts may decrease the absorption of iron, zinc and strontium ranelate. Consequently, iron, zinc or strontium ranelate preparations should be taken two hours before or after calcium carbonate.

4.6. Pregnancy and lactation

Pregnancy
Calcimore can be used during pregnancy. Daily intake should not exceed 2500 mg of calcium as permanent hypercalcaemia has been related to adverse effects on the developing foetus.

Breastfeeding
Calcium carbonate can be used during breast-feeding. Calcium passes into breast milk but at therapeutic doses no effects on the breastfed new-born are anticipated.

4.7. Effects on ability to drive and use machines

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

4.8. Undesirable effects

Adverse reactions are listed below, by system organ class and frequency. Frequencies are defined as: uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000) or very rare (<1/10,000).

Metabolism and nutrition disorders
Uncommon: Hypercalcaemia and hypercalciuria.
Very rare: Milk-alkali syndrome (frequent urge to urinate; continuing headache; continuing loss of appetite; nausea or vomiting; unusual tiredness or weakness; hypercalcaemia, alkalosis and renal impairment). Seen usually only in overdose (see section 4.9).

Gastrointestinal disorders
Rare: Constipation, dyspepsia, flatulence, nausea, abdominal pain and diarrhoea.
'Acid Rebound' has been reported on cessation of calcium carbonate.

Skin and subcutaneous disorders
Very rare: Pruritus, rash and urticaria.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions by using an online form https://sideeffects.health.gov.il/

4.9. Overdose

Overdose can lead to hypercalcaemia. Symptoms of hypercalcaemia may include anorexia, thirst, nausea, vomiting, constipation, abdominal pain, muscle weakness, fatigue, mental disturbances, polydipsia, polyuria, bone pain, nephrocalcinosis, nephrolithiasis 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 still occur in patients who ingest large amounts of calcium and absorbable alkali. It is not uncommon as a cause of hypercalcaemia requiring hospitalisation. The syndrome has also been reported in a patient taking recommended doses of antacids containing calcium carbonate for chronic epigastric discomfort, and in a pregnant woman taking high, but not grossly excessive, doses of calcium (about 3 g of elemental calcium daily). Metastatic calcification can develop.

Treatment of hypercalcaemia: The treatment with calcium must be discontinued. Treatment with thiazide diuretics, lithium, vitamin A, vitamin D and cardiac glycosides must also be discontinued. Treatment: rehydration, and, according to severity of hypercalcaemia, isolated or combined treatment with loop diuretics, bisphosphonates, calcitonin and corticosteroids should be considered. Serum electrolytes (if necessary with intravenous 0.9% sodium chloride), renal function and diuresis must be monitored. In severe cases, ECG and CVP should be followed.

5. Pharmacological properties

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: Mineral supplements: Calcium antiacid
ATC-code: A12AA04
An adequate intake of calcium is of importance during growth, pregnancy and breastfeeding.

Mechanism of Action/Effect (antiacid)
Calcium Carbonate reacts chemically to neutralise or buffer existing quantities of stomach acid but has no direct effect
on its output. This action results in increased pH value of stomach contents, thus providing relief of hyperacidity
symptoms. It also reduces acid concentration within the lumen of the oesophagus, thus causing an increase in intraoesophageal
pH and a decrease in pepsin activity, which aids the control of gastro-oesophageal reflux.

5.2. Pharmacokinetic properties

Absorption: The amount of calcium absorbed through the gastrointestinal tract is approximately 30% of the swallowed dose.
Distribution and biotransformation: 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.
Excretion and elimination: Calcium is eliminated through faeces, urine and sweat. Renal excretion depends on glomerular filtration and calcium tubular reabsorption.

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

Mannitol, sucrose, talc, magnesium stearate, spearmint flavor, peppermint flavor, sodium saccharine.

6.2. Incompatibilities

Not Applicable.

6.3. Shelf life

The expiry date of the product is indicated on the packaging materials.

6.4. Special precautions for storage

Store below 25^0C.

6.5. Nature and contents of container

Blisters of 10, 20, 50, 60, 100 and 1000 tablets.
Not all packs may be marketed.

6.6. Special precautions for disposal and other handling

No special requirements.

7. Marketing authorization holder

Taro Pharmaceutical Industries Ltd., 14 Hakitor St., Haifa Bay 2624761

8. Marketing authorization number(s)

015.95.24731

9. Date of revision of the text

The content of this leaflet was approved by the Ministry of Health in September 2021.