SUMMARY OF THE PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Calcitugg 500 mg chewable tablets
Calcitugg 1000 mg chewable tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One tablet of 500 mg contains:
Calcium carbonate equivalent to 500 mg calcium

One tablet of 1000 mg contains:
Calcium carbonate equivalent to 1000 mg calcium

Excipients with known effect:
Isomalt (E953)

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Chewable tablet

Round, white, uncoated and convex tablets. May have small specks.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Prevention and treatment of calcium deficiency. Calcium supplement as an adjunct to specific therapy in the prevention and treatment of osteoporosis. Phosphate binder in hyperphosphataemia.

4.2 Posology and method of administration

Posology

Adults
Prevention and treatment of calcium deficiency
Adjunctive therapy in osteoporosis
500 – 1500 mg per day

Hyperphosphataemia
Individual dosage. 2-8 g calcium daily is often required divided into 2-4 doses. The tablets should be taken with meals in order to bind phosphate in the food.

Special patient populations

Paediatric population
Prevention and treatment of calcium deficiency
500 – 1000 mg per day

Method of administration
Oral. The tablet should be chewed or sucked.

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
- Renal calculi (nephrolithiasis)

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 of calcium levels is important in patients on concomitant treatment with cardiac glycosides 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 with subsequent kidney function impairment. In these patients serum calcium levels should be followed and renal function should be monitored.

Calcitugg tablets contain isomalt (E953). Patients with rare hereditary problems of fructose intolerance, should not take this medicine.

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.

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 one hour before the intake of Calcitugg 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 six hours 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 at least two hour before or after calcium carbonate.

4.6 Fertility, pregnancy and lactation

Pregnancy
Calcium carbonate 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 breastfeeding. 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 the 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, flatulence, nausea, abdominal pain, and diarrhoea.
Not known: Dyspepsia

Skin and subcutaneous tissue 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 via the national reporting system listed in Appendix V*.

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, polidipsia, 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.

Treatment: The treatment with calcium must be discontinued. Treatment with thiazide diuretics, vitamin D and cardiac glycosides must also be discontinued. Emptying of the stomach in patients with impaired consciousness. Rehydration, and, according to severity, isolated or combined treatment with loop diuretics, bisphosphonates, calcitonin and corticosteroids. Serum electrolytes, 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: Calcium
ATC-code: A12A A04
An adequate intake of calcium is of importance during growth, pregnancy and breastfeeding.

5.2 Pharmacokinetic properties

Calcium

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.
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 SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Xylitol (E967)
Povidone
Isomalt (E953)
Flavouring (orange)
Magnesium Stearate
Sucralose (E955)
Mono- and diglycerides of fatty acids

6.2 Incompatibilities

Not applicable

6.3 Shelf-life

500 mg:
High Density Polyethylene tablet container: 3 years

1000 mg:
High Density Polyethylene tablet container: 3 years

After opening: 6 months

Blister pack: 2 years

6.4 Special precautions for storage

High Density Polyethylene tablet container: Do not store above 30°C.
Keep the container tightly closed in order to protect from moisture.
Blister pack: Do not store above 25°C. Store in the original package in order to protect from moisture.

6.5 Nature and content of container

The chewable tablets are packed in:
High Density Polyethylene tablet containers
Pack sizes: 20, 30, 50, 60, 90, 100, 120 and 180 tablets (500 mg)
30, 60, 90, 100 tablets (1000 mg)
Blister pack (PVC/PE/PVdC/AI)
Package size: 50 x 1 tablets (unit dose)

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements

7 MARKETING AUTHORISATION HOLDER

8 [TO BE COMPLETED NATIONALLY]MARKETING AUTHORISATION NUMBERS

9 [TO BE COMPLETED NATIONALLY]DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: {DD month YYYY}
Date of last renewal: {DD month YYYY}

10 [TO BE COMPLETED NATIONALLY]DATE OF REVISION OF THE TEXT

[To be completed nationally] 2023-04-12