

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Calcium-Sandoz 500 mg effervescent tablets

Calcium-Sandoz 1000 mg effervescent tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each effervescent tablet of 500 mg contains 1132 mg of calcium lactate gluconate and 875 mg of calcium carbonate (equivalent to 500 mg or 12.5 mmol of calcium).

Excipients with known effect

Each effervescent tablet of 500 mg contains, 30 mg of aspartame (E 951), 68.45 mg of sodium (2.98 mmol), 30 mg of orange flavour powder (containing 630 microgram sorbitol (E 420), 180 nanogram of benzyl alcohol, 210 nanogram sulphur dioxide (E 220), and 13.08 mg glucose).

Each effervescent tablet of 1000 mg contains 2263 mg of calcium lactate gluconate and 1750 mg of calcium carbonate (equivalent to 1000 mg or 25 mmol of calcium).

Excipients with known effect

Each effervescent tablet of 1000 mg contains, 30 mg of aspartame (E 951), 136.90 mg of sodium (5.95 mmol), 30 mg of orange flavour powder (containing 630 microgram sorbitol (E 420), 180 nanogram of benzyl alcohol, 210 nanogram sulphur dioxide (E 220) and 13.08 mg glucose).

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Effervescent tablet

White, circular, flat faced, bevelled edge effervescent tablets with an orange odour

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
- Rickets and osteomalacia, in addition to vitamin D3 therapy

4.2 Posology and method of administration

Adults: 500 – 1500 mg per day

Children: 500 – 1000 mg per day

The effervescent tablets should be dissolved in a glass of water (approx. 200 ml) and drunk immediately. Calcium Sandoz effervescent tablet may be taken with or without food.

4.3 Contraindications

- Hypersensitivity to the active substances or to any of the excipients listed in section 6.1 of the effervescent tablet
- Diseases and/or conditions resulting in hypercalcaemia and/or hypercalciuria
- Nephrocalcinosis, nephrolithiasis

4.4. Special warnings and precautions for use

For patients with mild hypercalciuria (exceeding 300 mg/24 hours or 7.5 mmol/24 hours), or with a history of urinary calculi, monitoring of calcium excretion in the urine is required. If necessary, the calcium dose should be reduced or therapy should be discontinued. An increased fluid intake is recommended for patients prone to formation of calculi in the urinary tract.

In patients with impaired renal function, calcium salts should be taken under medical supervision with monitoring of calcium and phosphate serum levels.

During high dose therapy and especially during concomitant treatment with vitamin D, there is a risk of hypercalcaemia with subsequent kidney function impairment. In these patients serum calcium levels should be followed and renal function should be monitored.

There have been literature reports alluding to possible increased absorption of aluminium with citrate salts. Calcium Sandoz effervescent tablet (which contains 1662.00 mg (500 mg tablet) or 3323.0 mg (1000 mg tablet) of citric acid) should be used with caution in patients with severely impaired renal function, especially those also receiving aluminium-containing preparations.

Calcium Sandoz 500 mg contains aspartame, sodium, sorbitol, benzyl alcohol and sulphur dioxide and glucose

This medicine contains 630 microgram sorbitol (E 420) in each tablet.

This medicinal product contains 2.98 mmol (corresponding to 68.45 mg) sodium per effervescent tablet, equivalent to 3.4 % of the WHO recommended maximum daily intake of 2 g sodium for an adult.

This medicine contains 180 nanogram benzyl alcohol in each tablet. Benzyl alcohol may cause allergic reactions. Intravenous administration of benzyl alcohol has been associated with serious adverse events and death in neonates ("gasping syndrome"). The minimum amount of benzyl alcohol at which toxicity may occur is not known. Increased risk due to accumulation in young children. High volumes should be used with caution and only if necessary, especially in patients who are pregnant or breast-feeding and in subjects with liver or kidney impairment because of the risk of accumulation and toxicity (metabolic acidosis).

This medicine contains 210 nanogram sulphur dioxide that may rarely cause severe hypersensitivity reactions and bronchospasm.

This medicine contains 30 mg aspartame in each effervescent tablet. Aspartame is a source of phenylalanine and may be harmful for people with phenylketonuria.

This medicine contains glucose. Patients with rare glucose-galactose malabsorption should not take this medicine. It may also be harmful to the teeth.

Calcium Sandoz 1000 mg contains aspartame, sodium, sorbitol, benzyl alcohol, sulphur dioxide and glucose

This medicine contains 630 microgram sorbitol (E 420) in each tablet.

This medicinal product contains 5.95 mmol (corresponding to 136.90 mg) sodium per tablet, equivalent to 6.9 % of the WHO recommended maximum daily intake of 2 g sodium for an adult.

This medicine contains 180 nanogram benzyl alcohol in each tablet. Benzyl alcohol may cause allergic reactions. Intravenous administration of benzyl alcohol has been associated with serious adverse events and death in neonates (“gasping syndrome”). The minimum amount of benzyl alcohol at which toxicity may occur is not known. Increased risk due to accumulation in young children. High volumes should be used with caution and only if necessary, especially in subjects with liver or kidney impairment because of the risk of accumulation and toxicity (metabolic acidosis).

This medicine contains 210 nanogram sulphur dioxide that may rarely cause severe hypersensitivity reactions and bronchospasm.

This medicine contains 30 mg aspartame in each effervescent tablet. Aspartame is a source of phenylalanine, and may be harmful for people with phenylketonuria.

This medicine contains glucose. Patients with rare glucose-galactose malabsorption should not take this medicine. It may also be harmful to the teeth.

Calcium Sandoz effervescent tablets should be kept out of the reach of children.

Information for diabetics:

One effervescent tablet contains 0.002 Carbohydrate Units and is therefore suitable for diabetics.

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.

Systemic corticosteroids reduce calcium absorption. During concomitant use, it may be necessary to increase the dose of Calcium Sandoz.

Tetracycline preparations administered concomitantly with calcium preparations may not be well-absorbed. For this reason, tetracycline preparations should be administered at least two hours before or four to six hours after oral intake of calcium.

Cardiac glycoside toxicity may increase with hypercalcaemia resulting from treatment with calcium. Patients should be monitored with regard to electrocardiogram (ECG) and serum calcium levels.

If an oral bisphosphonate or sodium fluoride is used concomitantly, this preparation should be administered at least three hours before the intake of Calcium Sandoz since gastrointestinal absorption of either oral bisphosphonate or sodium fluoride may be reduced.

Oxalic acid (found in spinach and rhubarb) and phytic acid (found in whole cereals) may inhibit calcium absorption through formation of insoluble compounds with calcium ions. The patient should not take calcium products within two hours of eating foods high in oxalic acid and phytic acid.

4.6. Fertility, pregnancy and lactation

The adequate daily intake (including food and supplementation) for normal pregnant and lactating women is 1000-1300 mg calcium.

During pregnancy, the daily intake of calcium should not exceed 1500 mg. Significant amounts of calcium are secreted in milk during lactation but do not cause any adverse effects to the neonate.

Calcium Sandoz effervescent tablets can be used during pregnancy and lactation in case of a calcium deficiency

4.7. Effects on ability to drive and use machines

Calcium Sandoz has no 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, <1/100), *rare* (>1/10,000, <1/1,000) or *very rare* (<1/10,000), including isolated reports.

Immune system disorders:

Rare: Hypersensitivity, such as rash, pruritus, urticaria.

Very rare: Isolated cases of systemic allergic reactions (anaphylactic reaction, face oedema, angioneurotic oedema) have been reported

Metabolism and nutrition disorders:

Uncommon: Hypercalcaemia, hypercalciuria

Gastrointestinal disorders:

Rare: flatulence, constipation, diarrhoea, nausea, vomiting, abdominal pain

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 leads to hypercalciuria and hypercalcaemia. Symptoms of hypercalcaemia may include: nausea, vomiting, thirst, polydipsia, polyuria, dehydration and constipation. Chronic overdose with resulting hypercalcaemia can cause vascular and organ calcification.

The threshold for calcium intoxication is from supplementation in excess of 2000 mg per day, taken for several months.

Treatment of overdose:

In the case of an intoxication, treatment should be stopped immediately and the fluid deficiency should be corrected.

In case of chronic overdose where hypercalcaemia is present, the initial therapeutic step is hydration with saline solution. A loop diuretic (e.g., furosemide) may then be used to further increase calcium excretion and to prevent volume overload, but thiazide diuretics should be

avoided. In patients with renal failure, hydration is ineffective and they should undergo dialysis. In the case of persistent hypercalcaemia, contributing factors should be excluded, e.g., vitamin A or D hypervitaminosis, primary hyperparathyroidism, malignancies, renal failure, or immobilisation.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: Mineral supplements

ATC codes: Calcium carbonate (A 12 AA 04), Calcium lactate gluconate (A 12 AA 06)

Calcium is an essential mineral, necessary for bone formation and maintenance, for electrolyte equilibrium in the body and for the proper functioning of numerous regulatory mechanisms.

5.2 Pharmacokinetic properties

Calcium Sandoz contains two calcium salts, calcium lactate gluconate and calcium carbonate, which readily dissolve in water to make the active ionised form of calcium freely usable.

Absorption:

Some 25-50% of the ingested dose of calcium is absorbed, predominantly in the proximal part of the small intestine, and delivered to the exchangeable calcium pool.

Distribution and metabolism:

The mineral component of bones and teeth contains 99% of the body's calcium. 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 5% being complexed to citrate, phosphate or other anions. The remaining 45% of serum calcium is bound to proteins, principally albumin.

Elimination:

Calcium is excreted in the urine, faeces and sweat. Urinary excretion depends on glomerular filtration and 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

Citric acid anhydrous (fine granulate)

Orange flavour powder (contains benzyl alcohol, sorbitol (E 420), glucose and sulphur dioxide (E 220))

Aspartame (E 951)

Macrogol 6000

Sodium hydrogen carbonate

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

3 years.

6.4. Special precautions for storage

Keep the tube tightly closed. Store in the original package.

6.5. Nature and contents of container

The effervescent tablets are packed in polypropylene tubes and tamperproof polyethylene stoppers with desiccant, each containing 10 or 20 tablets. The tubes are packed in boxes containing 10, 20, 30, 40, 60, 80, 100 and 600 (for 500 mg tablets only) tablets.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal <and other handling>

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

To be completed nationally.

8. MARKETING AUTHORISATION NUMBER(S)

To be completed nationally.

9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

Date of first authorisation: {DD month YYYY}

Date of latest renewal: {DD month YYYY}

10. DATE OF REVISION OF THE TEXT

2020-01-17