

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Sandocal 1000 Effervescent Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each effervescent tablet of 1000 mg contains:

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

Excipients:

3323mg of citric acid anhydrous (fine granulate), 30mg of aspartame (E 951), 500 mg of sodium hydrogen carbonate, 30 mg of Orange flavour powder (containing sorbitol (E 420) and dextrose).

For a 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. Sandocal effervescent tablet may be taken with or without food.

4.3 Contraindications

- Hypersensitivity to the active substances or to any of the excipients 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. Sandocal effervescent tablet (which contains citric acid) should be used with caution in patients with severely impaired renal function, especially those also receiving aluminium-containing preparations.

Each Sandocal effervescent tablet contains aspartame, a source of phenylalanine equivalent to 15 mg/dose, and may be harmful for people with phenylketonuria.

Patients with rare hereditary problems of fructose intolerance or glucose-galactose malabsorption should not take this medicine.

Sandocal 1000 mg contains 5.95 mmol (corresponding to 136.90 mg) of sodium per tablet.

Sandocal 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 Sandocal.

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 Sandocal 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 1000-1300mg 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.

Sandocal 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

Sandocal 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

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

Sandocal 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: orange essential oils, maltodextrin, arabic gum, sorbitol (E 420), dextrose)

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 and 100 tablets.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

GlaxoSmithKline Consumer Healthcare (Ireland) Limited

12 Riverwalk

Citywest Business Campus

Dublin 24

Ireland

8 MARKETING AUTHORISATION NUMBER

PA0678/132/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 25 January 1988

Date of last renewal: 13 March 2007

10 DATE OF REVISION OF THE TEXT

March 2017