

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Calcium Sandoz Syrup

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 15ml contains 3.27g calcium glubionate and 2.18g calcium lactobionate. Three 5ml spoonfuls provide 325mg calcium (8.1 mmol:16.2mEq Ca++)

Each 15ml also contains 4.54g of Sucrose.

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Syrup
Colourless to pale straw-coloured, fruit flavoured syrup

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

High-dose oral calcium in the form of Calcium Sandoz Syrup is indicated in the treatment of neonatal tetany, and as a therapeutic supplement in osteoporosis, post-gastrectomy malabsorption, osteomalacia, rickets, pregnancy and lactation.

4.2 Posology and method of administration

Oral Indication	Daily dosage Syrup
Osteoporosis	
Post-gastrectomy malabsorption	60 – 100 ml
Osteomalacia and rickets	
Lactation	20 – 60 ml
Pregnancy supplement	

Use in children

The usual total daily dose is 30-50 ml.

Neonatal hypocalcaemia: Calcium-Sandoz Syrup may be given at a dose of 1 mmol calcium/kg/24 hours in divided doses.

Serum calcium levels should be monitored and the dosage adjusted if necessary. Doses may be mixed with the first (small) part of milk feeds.
Note: 1 mmol of calcium is equivalent to 1.85 Calcium-Sandoz Syrup.

Use in the elderly

No evidence exists that dosage or tolerance of Calcium Sandoz Syrup is directly affected by advanced age; however, elderly patients should be supervised as factors sometimes associated with ageing, such as poor diet or impaired renal function, may indirectly affect dosage or tolerance. (see also Precautions).

4.3 Contraindications

Severe hypercalcaemia and hypercalciuria (e.g. in hyperparathyroidism, vitamin D overdosage, decalcifying tumours such as plasmocytoma and skeletal metastases, immobilisation osteoporosis; sarcoidosis), severe renal failure and milk-alkali syndrome.

Due to its galactose component Calcium-Sandoz Syrup should not be given to patients with galactosaemia.

4.4 Special warnings and precautions for use

Use with caution in patients with impaired renal function or with nephrocalcinosis, or in the elderly.

The use of calcium salts should be accompanied by a careful surveillance to ensure maintenance of correct calcium balance.

4.5 Interaction with other medicinal products and other forms of interaction

High vitamin D intake should be avoided during calcium therapy, unless especially indicated.

The effects of digoxin and other cardiac glycosides may be accentuated.

Tetracycline absorption may be reduced if given concomitantly with oral calcium.

4.6 Fertility, pregnancy and lactation

The likelihood of hypercalcaemia is increased in pregnant women in whom calcium and vitamin D are co-administered.

Epidemiological studies with calcium have shown no increase in the teratogenic hazard to the foetus is used in doses recommended.

Although supplemental calcium may be excreted in breast milk, the concentration is unlikely to be sufficient to produce any adverse effect on the neonate.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Mild gastrointestinal disturbances have occurred rarely (e.g. constipation, diarrhoea). Although hypercalcaemia would not be expected in patients unless their renal function were impaired, the following symptoms could indicate the possibility of hypercalcaemia: nausea, vomiting, anorexia, constipation, abdominal pain, bone pain, thirst, polyuria, muscle weakness, drowsiness or confusion.

4.9 Overdose

The amount of calcium absorbed following overdosage with Calcium Sandoz Syrup will depend on the individual's status. Deliberate overdosage is unlikely with effervescent preparations and acute overdosage has not been reported. It might cause gastrointestinal disturbances but would not be expected to cause hypercalcaemia except in patients treated with excessive doses of vitamin D. Treatment should be aimed at lowering serum calcium levels, e.g. administration of oral phosphates.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Calcium is an essential body electrolyte. It is involved in the maintenance of normal tissue and nerve function, is essential for normal cardiac function and is essential to blood coagulation. There is dynamic equilibrium between the calcium in blood and that in skeleton. Homeostasis is mainly regulated by parathyroid hormone, by calcitonin and by vitamin D.

5.2 Pharmacokinetic properties

5.3 Preclinical safety data

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzoic acid
Formic acid
Sucrose
Orange 'natural' flavour
Tamaris flavour
Purified water.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 25°C. Keep the container tightly closed to protect from moisture.

6.5 Nature and contents of container

500ml and 300ml amber, glass bottles with a polypropylene closure (polyethylene wad face with PP, PVDC or PET lining).

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

Calcium-Sandoz Syrup may be diluted with Syrup BP; the diluted syrup should be used within 14 days. Calcium-Sandoz Syrup contains 1.512g sucrose per 5ml (4.536g sucrose per 15ml dose). Approximate calorific value of 13kcal per 5ml (39kcal per 15ml dose).

7 MARKETING AUTHORISATION HOLDER

GlaxoSmithKline Consumer Healthcare (Ireland) Limited
12 Riverwalk
Citywest Business Campus
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Ireland

8 MARKETING AUTHORISATION NUMBER

PA0678/127/001

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