

IRISH MEDICINES BOARD ACT 1995, as amended

Medicinal Products (Control of Placing on the Market) Regulations, 2007, as amended

PA0030/046/001

Case No: 2043300

The Irish Medicines Board in exercise of the powers conferred on it by the above mentioned Regulations hereby grants to

Novartis Consumer Health UK Limited

Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom

an authorisation, subject to the provisions of the said Regulations, in respect of the product

Sandocal 400 mg Effervescent Tablets

the particulars of which are set out in the attached Schedule. The authorisation is also subject to the general conditions as may be specified in the said Regulations as listed on the reverse of this document.

This authorisation, unless previously revoked, shall continue in force from **01/04/2008**.

Signed on behalf of the Irish Medicines Board this

A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Sandocal 400 mg Effervescent Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

931 mg calcium lactate gluconate and 700 mg calcium carbonate providing 400 mg calcium (10 mmol: 20 mEq Ca⁺⁺).

Excipients: also includes Aspartame (E951) 16 mg per tablet and Orange flavour (containing sulphites) 28 mg per tablet

For a full list of excipients, see Section 6.1.

3 PHARMACEUTICAL FORM

Effervescent tablet

White, round, flat-faced, effervescent tablet with a slightly rough surface weighing 2.92 g, 25 mm diameter and 4.35 mm thick, citrus flavoured.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

High-dose oral calcium in the form of Sandocal 400 Effervescent Tablets are 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: Daily dosage

<u>Indication</u>	<u>Daily dosage</u>
	Effervescent Tablets (The tablets must be in 1/3 - 1/2 tumbler full of water).
Osteoporosis	
Post-gastrectomy malabsorption	3-5 tablets
Osteomalacia and rickets	
Lactation	
Pregnancy supplement	1-3 tablets

Use in children

Children require about half the adult dosage.

Use in the elderly

No evidence exists that dosage or tolerance of Sandocal 400 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 overdose, decalcifying tumours such as plasmocytoma and skeletal metastases, immobilisation osteoporosis; sarcoidosis), severe renal failure and milk-alkali syndrome.

4.4 Special warnings and precautions for use

Use with caution in patients with impaired renal function or with nephrocalcinosis.

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

Sandocal 400 mg Effervescent tablets contain aspartame, a source of phenylalanine. May be harmful for people with phenylketonuria.

The orange flavour contains sulphites which may rarely cause severe hypersensitivity reactions and bronchospasm.

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 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 if 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 overdose with Sandocal 400 will depend on the individual's status. Deliberate overdose is unlikely with effervescent preparations and acute overdose 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 a 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

Not applicable.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Anhydrous citric acid (fine granulate)
Macrogol 4000
Orange flavour (containing sulphites)
Aspartame (E951)

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 tube tightly closed. Store in the original package to protect from moisture.

6.5 Nature and contents of container

Polypropylene tubes with polyethylene caps containing integral silica gel desiccant capsule. Cartons of 5 tubes, each tube containing 20 tablets.

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

Novartis Consumer Health UK Ltd
Trading As:

Novartis Consumer Health
Wimblehurst Road
Horsham
West Sussex RH 12 5AB
United Kingdom.

8 MARKETING AUTHORISATION NUMBER

PA 30/46/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 April 1983

Date of last renewal: 01 April 2008

10 DATE OF REVISION OF THE TEXT

July 2010