

## PACKAGE LEAFLET: INFORMATION FOR THE USER

# Sandocal® 1000 Effervescent Tablets

## Calcium

**Read all of this leaflet carefully because it contains important information for you.**

This medicine is available without prescription. However, you still need to take Sandocal carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

### In this leaflet

1. What Sandocal is and what it is used for
2. Before you take Sandocal
3. How to take Sandocal
4. Possible side effects
5. How to store Sandocal
6. Further information

## 1. WHAT SANDOCAL IS AND WHAT IT IS USED FOR

Sandocal contains a rich source of calcium which is an essential mineral, necessary for bone formation and maintenance.

Sandocal is used in the prevention and treatment of calcium deficiency, and may be used, with other medicines, to prevent and treat a condition called osteoporosis (weakening of the bones). Sandocal is also used, together with vitamin D3, for the treatment of rickets (softening of growing bones in children) and osteomalacia (softening of adults bones).

Calcium is absorbed from the intestine and distributed throughout the body in the blood. Calcium plays an important role in several body functions. It is essential for nerve, muscle and heart function as well as for the clotting of blood.

In addition, it is necessary for many hormones to work properly in the body. To carry out these various roles, calcium must be available in the appropriate concentration.

## 2. BEFORE YOU TAKE SANDOCAL

### Do not take Sandocal...

- If you are allergic to calcium and any of the other ingredients of Sandocal (*see the list of ingredients in section 6 at the end of the leaflet*).
- If you are suffering from raised levels of blood calcium (hypercalcaemia);
- If you are suffering from increased calcium in your urine (hypercalciuria);
- If you are suffering from certain kidney problems including: kidney stones (nephrolithiasis) and calcium deposits in your kidney tissue (nephrocalcinosis).

### **Take special care...**

- If you suffer from a kidney disease, only take Sandocal after consulting your doctor, and especially if you are taking preparations containing aluminium.
- Do not take vitamin D products together with Sandocal without medical advice.

### **Taking other medicines**

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a medical prescription because calcium can interact with certain other medicines if taken at the same time.

- If you are taking, or have recently taken, cardiac glycosides, thiazide diuretics, or corticosteroids, you must follow your doctor's instructions carefully.
- If you are taking oral bisphosphonates or sodium fluoride, take Sandocal at least 3 hours after these medicines.
- If you are taking one of a group of antibiotics called tetracyclines, take Sandocal at least 2 hours after or 4-6 hours before the tetracycline.

### **Taking Sandocal with food and drink**

- Sandocal should not be taken within 2 hours of eating foods high in oxalic or phytic acid such as spinach, rhubarb and whole cereals.

### **Pregnancy or breast-feeding**

- Ask your doctor or pharmacist before taking Sandocal if you are pregnant or breast-feeding.
- Sandocal can be used during pregnancy and breast-feeding in case of a calcium deficiency. In general, the adequate daily intake (including food and supplementation) for pregnant and breastfeeding women is 1000 – 1300 mg calcium. The total daily intake of calcium during pregnancy and breast-feeding should not exceed 1500 mg.
- Calcium passes into breast-milk but has no negative effect on the baby.

### **Driving and using machines**

- There is no known effect on the ability to drive or operate machines caused by taking Sandocal.

### **Important information about some of the ingredients of Sandocal**

- Sandocal is suitable for diabetics (1 effervescent tablet of 1000 mg contains 0.002 Carbohydrate Units).
- Patients on a controlled sodium diet should seek advice from health professionals prior to taking Sandocal. Sandocal 1000 mg contains 136.90 mg of sodium per tablet.
- If you think you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
- Sandocal contains aspartame, a source of phenylalanine, and may be harmful for people with phenylketonuria.

## **3. HOW TO TAKE SANDOCAL**

As with all medicinal products, please follow all of the instructions carefully to ensure that Sandocal works properly.

- For Sandocal 1000 mg:
  - Children and adults take one effervescent tablet (one single dose) once per day.

Dissolve Sandocal in a glass of water (approximately 200 ml) and drink immediately.

Do not swallow or chew the tablet.

Sandocal can be taken with or without food (*see the section "Taking Sandocal with food and drink" for further advice*).

### **How long should you take Sandocal**

Take Sandocal at the recommended daily dose for as long as you are advised by your doctor. As Sandocal is used in the prevention and treatment of calcium deficiency and, taken with other medicines, in the prevention and treatment of a condition called osteoporosis (weakening of the bones), it is likely this will be a long term treatment.

### **If you take more Sandocal than you should**

Overdose of Sandocal may lead to symptoms such as nausea, vomiting, thirst or constipation. If overdose is suspected, contact your doctor or pharmacist immediately.

### **If you forget to take Sandocal**

Do not take a double dose to make up for a forgotten dose.

## **4. POSSIBLE SIDE EFFECTS**

Like all medicines, Sandocal can cause side effects although not everybody gets them.

- Very rare side effects (*occur in less than 1 in 10'000 people*) include:
  - severe allergic reactions such as swelling of the face, lips, tongue and/or throat, which may cause difficulty in swallowing.

If you experience any of the above listed allergic reactions, STOP taking Sandocal and tell your doctor immediately.

- Rare side effects (*occur in less than 1 person out of 1'000*) include:
  - nausea, diarrhoea, abdominal pain, constipation, flatulence, vomiting, itching, redness and/or burning of the skin.
- Uncommon side effects (*occur in less than 1 person out of 100*) may include:
  - excessive calcium level in the blood (hypercalcaemia) or excessive excretion of calcium in the urine (hypercalciuria).

If any of the side effects get serious or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

## **5. HOW TO STORE SANDOCAL**

- Keep out of the reach and sight of children.
- Expiry date:
  - Do not take Sandocal after the expiry date stated on the box and on the tube after "EXP". The expiry date refers to the last day of that month.
- Storage conditions:
  - Store in the original package and keep the tube tightly closed.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## 6. FURTHER INFORMATION

### What Sandocal contains

The active substances are calcium lactate gluconate and calcium carbonate.

- Each tablet of 1000 mg contains 2263 mg of calcium lactate gluconate and 1750 mg of calcium carbonate (equivalent to 1000 mg of calcium).

The other ingredients are: citric acid anhydrous, orange flavouring (contains: orange essential oils, maltodextrin, arabic gum, sorbitol (E 420), dextrose), aspartame (E 951), macrogol 6000 and sodium hydrogen carbonate.

### What Sandocal looks like and contents of the pack

The effervescent tablet is white and circular with a characteristic orange odour.

Sandocal 1000 mg is available in packs of 30 effervescent tablets.

Not all pack sizes may be marketed

### This medicinal product is authorized in the Member States of the EEA under the following names:

Austria:	Mega-Calcium-Brausetabletten
Czech Republic:	CALCIUM-SANDOZ® FF 1000mg
Finland:	Mega-Calcium 1g poretabletti
Germany:	Calcium-Sandoz® fortissimum 1000mg
Greece:	Mega-Calcium® Sandoz
Ireland:	Sandocal 1000
Italy:	CALCIUM-SANDOZ 1000 mg compresse effervescenti
Luxembourg:	Calcium-Sandoz® fortissimum 1000mg
The Netherlands:	Sandoz Calcium fortissimum, bruistabletten
Slovakia:	CALCIUM-SANDOZ® FF 1000 mg
Sweden:	Calcium-Sandoz 1000 mg, brustabletter
UK:	Sandocal 1000

### Marketing authorisation holder/manufacturer:

The marketing authorisation holder is:

GlaxoSmithKline Consumer Healthcare (Ireland) Limited, 12 Riverwalk, CityWest Business Campus, Dublin 24, Ireland.

The manufacturer is:

GlaxoSmithKline Consumer Healthcare (UK) Trading Limited, Brentford, TW8 9GS, U.K.

### This leaflet was last revised in

June 2016.