

Package leaflet: Information for the patient

Calcium Sandoz 500 mg effervescent tablets Calcium Sandoz 1000 mg effervescent tablets

calcium

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse.

What is in this leaflet

1. What Calcium Sandoz is and what it is used for
2. What you need to know before you take Calcium Sandoz
3. How to take Calcium Sandoz
4. Possible side effects
5. How to store Calcium Sandoz
6. Contents of the pack and other information

1. What Calcium Sandoz is and what it is used for

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

Calcium Sandoz 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).

Calcium Sandoz 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. What you need to know before you take Calcium Sandoz

Do not take Calcium Sandoz:

- If you are allergic to calcium and any of the other ingredients of Calcium Sandoz (*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).

Warnings and precautions

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

Other medicines and Calcium Sandoz

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 doctors instructions carefully.
- If you are taking oral bisphosphonates or sodium fluoride, take Calcium Sandoz at least 3 hours after these medicines.
- If you are taking one of a group of antibiotics called tetracyclines, take Calcium Sandoz at least 2 hours after or 4-6 hours before the tetracycline.

Calcium Sandoz with food and drink

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

Pregnancy and breast-feeding

- Ask your doctor or pharmacist before taking Calcium Sandoz if you are pregnant or breast-feeding.
- Calcium Sandoz 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 breast-feeding 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 Calcium Sandoz.

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

- Calcium Sandoz is suitable for diabetics (1 effervescent tablet of 500 mg or 1000 mg contains 0.002 Carbohydrate Units).
- *500 mg*: This medicine contains 68.45 mg of sodium (main component of cooking/table salt) in each effervescent tablet. This is equivalent to 3.4 % of the recommended maximum daily intake of sodium for an adult.
- *1000 mg*: This medicine contains 136.90 mg of sodium (main component of cooking/table salt) in each effervescent tablet. This is equivalent to 6.9 % of the recommended maximum daily intake of sodium for an adult.
- This medicine contains 180 nanogram benzyl alcohol in each effervescent tablet. Benzyl alcohol may cause allergic reactions. Benzyl alcohol has been linked with the risk of severe side effects including breathing problems (called “gasping syndrome”) in young children. Do not give to your newborn baby (up to 4 weeks old), unless recommended by your doctor. Do not use for more than a week in young children (less than 3 years old), unless advised by your doctor or pharmacist. Ask your doctor or pharmacist for advice if you are pregnant or breast-feeding. Ask your doctor or pharmacist for advice if you have a liver or kidney disease. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called “metabolic acidosis”).
- This medicine contains 210 nanogram sulphur dioxide that may rarely cause severe hypersensitivity reactions and bronchospasm.
- This medicine contains 30 mg aspartame (E 951) in each effervescent tablet. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up, because the body cannot remove it properly.
- This medicine contains 630 microgram sorbitol in each effervescent tablet.
- This medicine contains glucose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. It may be harmful to the teeth.

3. How to take Calcium Sandoz

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

- For Calcium Sandoz 500 mg:
 - Children take one effervescent tablet (one single dose) once or twice a day (equivalent to 500-1000 mg of calcium).
 - Adults take one effervescent tablet (one single dose) once, twice or three times a day (equivalent to 500-1500 mg of calcium).

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

Dissolve Calcium Sandoz in a glass of water (approximately 200 ml) and drink immediately. Do not swallow or chew the tablet.

Calcium Sandoz can be taken with or without food (*see the section “Taking Calcium Sandoz with food and drink” for further advice*)

How long should you take Calcium Sandoz

Take Calcium Sandoz at the recommended daily dose for as long as you are advised by your doctor. As Calcium Sandoz 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 Calcium Sandoz than you should

Overdose of Calcium Sandoz 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 Calcium Sandoz

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

4. Possible side effects

Like all medicines, Calcium Sandoz 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 Calcium Sandoz 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.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Calcium Sandoz

- Keep out of the reach and sight of children
- Expiry date:
Do not take Calcium Sandoz 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. Contents of the pack and other information

What Calcium Sandoz contains

The active substances are calcium lactate gluconate and calcium carbonate.

- Each tablet of 500 mg contains 1132 mg of calcium lactate gluconate and 875 mg of calcium carbonate (*equivalent to 500 mg of calcium*).
- 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 benzyl alcohol, sorbitol (E 420), glucose and sulphur dioxide (E 220)), aspartame (E 951), macrogol 6000 and sodium hydrogen carbonate.

What Calcium Sandoz looks like and contents of the pack

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

Calcium Sandoz 500 mg is packed in tubes of 10 or 20 effervescent tablets and is available in packs of 10, 20, 30, 40, 60, 80, 100 and 600 effervescent tablets.

Calcium Sandoz 1000 mg is packed in tubes of 10 or 20 effervescent tablets and is available in packs of 10, 20, 30, 40, 60, 80 and 100 effervescent tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

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

- For 500 mg effervescent tablets:

Austria:	Calcium Sandoz 500 mg - Brausetabletten
Belgium:	Sandoz Calcium, bruistabletten
Cyprus:	Calsource 500mg Effervescent Tablets
Czech Republic:	CALCIUM-SANDOZ® FORTE 500mg
Denmark:	Calcium-Sandoz, brusetabletter
France:	CALCIUM SANDOZ 500mg, comprimés effervescents
Hungary:	Calcium-Sandoz 500 mg pezsgőtabletta
Iceland:	Calcium-Sandoz, freyðitöflur
Italy:	CALCIUM-SANDOZ 500mg compresse effervescenti
Norway:	Calcium-Sandoz® 500mg brusetabletter
Poland:	CALCIUM-SANDOZ Forte
Portugal:	CALCIUM-SANDOZ® FORTE
Slovakia:	CALCIUM-SANDOZ® Forte 500 mg
Slovenia:	Calcium Calvive 500 mg šumeče tablete
Spain:	CalciumOsteo 500 mg comprimidos efervescentes
Sweden:	Calcium-Sandoz 500 mg, brustabletter

- For 1000 mg effervescent tablets :

Finland :	Mega-Calcium 1g poretabletti
Greece:	Calsource
Italy:	CALCIUM-SANDOZ 1000mg compresse effervescenti
Slovakia:	CALCIUM-SANDOZ® FF 1000mg
Sweden:	Calcium-Sandoz 1000 mg, brustabletter
UK:	Calvive

This leaflet was last revised in 2020-01-17.