

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS'
REGULATIONS (PREPARATIONS) - 1986**

This medicine can be sold without a doctor's prescription

Calcium D Sandoz, Effervescent Tablets

Active ingredients and their quantity in a dosage unit:

Calcium Lactate Gluconate 1.358 gr

Calcium Carbonate 1.050 gr

Equivalent to 600 mg available Calcium

Cholecalciferol Concentrate powder 4.00 mg (equivalent to 400 IU Vitamin D3)

For list of excipients, please see section 6.

Read this entire leaflet carefully before you start taking this medicine. This leaflet contains concise information about the medicine. If you have any further questions, ask your doctor or pharmacist. This medicine is intended for use in adults. Take in the correct manner. Consult your pharmacist if you need additional information.

1. What is the medicine used for?

A supplement of calcium and vitamin D in cases of deficiency and in periods of increased need for Calcium and vitamin D.

Therapeutic group: Calcium and vitamin D supplement

2. Before you take the medicine:

Do not use the medicine if:

- You are hypersensitive (allergic) to the active ingredients or to any of the other ingredients of this medicine.
- In cases of: excess of calcium in the blood, excess of calcium in the urine, severe kidney failure, kidney stones, excess of vitamin D in the blood.

Special warnings regarding the use of this medicine:

- **Before use consult your doctor:**
 - If you suffer from kidney disorders (especially if you take aluminum containing products), suffer from sarcoidosis, from severe mobility limitations due to osteoporosis.
 - During prolonged treatment, calcium levels in the blood and urine as well as renal function should be monitored.
 - Before taking additional calcium and vitamin D products.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including non-prescription drugs and nutrition supplements.

Especially inform your doctor or pharmacist if you are taking:

- Thiazide diuretics - can reduce urinary calcium excretion and cause hypercalcemia;
- Corticosteroids - reduce the absorption of calcium;
- Antibiotics of the tetracycline family - the use of calcium may reduce the absorption of these medicines, therefore they should be taken two hours before or about 4-6 hours after the use of calcium-containing products.
- Digitalis for the heart - the concomitant use with calcium products may increase digitalis toxicity. Should be monitored.
- Sodium fluoride or bisphosphonate taken orally - the concomitant use with calcium preparations may decrease the absorption of these products in the gastrointestinal system. Therefore, Bisphosphonate should be taken at least 3 hours before taking Calcium D.
- Cholestyramine and laxatives such as paraffin oil - may decrease the absorption of vitamin D in the gastrointestinal system. Calcium D Sandoz should be taken an hour before or 4-6 hours after taking these products.

Use of this medicine and food:

Take the medicine at any hour, with or without food.

Wait for a period of at least two hours between taking this medicine and eating foods containing oxalic acid (found in spinach and rhubarb) and phytic acid (found in foods rich in grains).

Pregnancy and breastfeeding:

You can use Calcium D Sandoz while breastfeeding and during pregnancy.

When the product is taken during the last trimester, do not exceed a dose of 1500 mg calcium and 600 IU vitamin D.

Driving and use of machinery:

The medicine does not affect the ability to drive or operate machinery.

Important information about some of the ingredients of this medicine:

Sorbitol and sucrose – patients suffering from disorders of these ingredients, should consult a doctor.

Information for diabetic patients:

Each tablet contains 0.003 carbohydrate units and thus allowed for use in diabetics.

3. How to use this medicine

Check with your doctor or pharmacist if you are not sure.

Usual recommended dosage:

Adults: 1 tablet 1-2 times a day, depending on diet.

Do not exceed the recommended dose.

Dissolve the tablet in a glass of water (about 200 ml) and drink immediately.

If you have accidentally taken a higher dosage you should discontinue treatment and refer to your doctor.

Overdose can be manifested as nausea, vomiting, thirst, excess drinking, increased urination, dehydration and constipation.

Prolonged overuse, that causes increased levels of calcium in the blood, can cause calcium sediments in the body.

If you have taken an overdose or if a child has accidentally swallowed the medicine, proceed immediately to a doctor or a hospital emergency room and bring the package of the medicine with you.

If you forget to take this medicine at the specified time, do not take a double dose. Take the next dose at the regular time.

Do not take medicines in the dark! Check the label and the dose each time you take your medicine. Wear glasses if you need them.

If you have any further questions regarding the use of this medicine, consult your doctor or pharmacist.

4. Side effects:

Like all medicines, Calcium D Sandoz can cause side effects, although not everybody gets them. Do not be alarmed while reading the list of side effects. You may not suffer from any of them.

Stop the use of this medicine and refer to your doctor immediately if:

- You feel one of the following symptoms that can indicate an allergic reaction: difficulty breathing and swallowing, swelling of the face, lips, tongue or throat, severe skin itching accompanied by a red rash and bumps on the skin.
These effects are rare and may occur in 1-10 users out of 10,000).

Additional side effects:

Side effects that appear uncommonly (at an incidence of 1:100 to 1:1,000): nausea, diarrhea, abdominal pain, constipation, flatulence, abdominal swelling, rash, vomiting, itching, bumps on the skin.

Severe side effects that appear rarely (at an incidence of 1:1,000 to 1:10,000): excess calcium in the blood, excess calcium in the urine.

If any of the side effects worsens, or if you experience side effects not mentioned in this leaflet, consult your doctor.

5. How to store the medicine

- Avoid poisoning! This medicine, and all other medicines, must be stored in a safe place out of the reach of children and/or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by your doctor.
- Do not use the medicine after the expiry date (exp. date) stated on the package. The expiry date refers to the last day of that month.
- Storage conditions: store below 30°C, in the original package. Keep the package tightly closed.

6. Additional information

In addition to the active ingredients this medicine also contains:

Citric Acid, Sodium Hydrogen Carbonate, Macrogol 6000, Aspartame, Orange Flavor Powder (contains: Orange Essential Oils, Maltodextrin, Arabic Gum, Sorbitol (E420) Dextrose), Sucrose, Cholecalciferol Concentrate Powder (contains: Sucrose, Bovine Gelatin Hydrolyzed, Maize Starch, Partially Hydrogenated Soya Oil, Alpha-Tocopherol).

Each tablet contains 82.14 mg sodium.

What does the medicine look like and what does the package contain?

Effervescent, white, flat tablets with beveled edges and an orange scent.

Marketed in packages of 60 effervescent tablets.

Registration holder: NCH Ltd., 14 Hamefalsim Street, Petach Tikva.

Manufacturer: Novartis Consumer Health SA, Nyon, Switzerland.

Drug registration number at the national medicines registry of the Ministry of Health:

139 45 31527

This leaflet was checked and approved by the Ministry of Health in 03/2014.

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