

Calcium/Vitamin D3 1000 mg/880 IU, chewable tablets

What is calcium/vitamin d3 and what is it used for?

This medicine contains the active ingredients calcium and vitamin D3. The product is a calcium-vitamin D3 supplement.

This medicine is used:

for the prevention and treatment of calcium and vitamin D deficiency in the elderly

as a vitamin D and calcium supplement to support the treatment of osteoporosis (brittle bones).

When should you not use this medicine or take extra caution?

When should you not use this medicine?

- if you are allergic to any of the substances in this medication. You can find these substances listed in section 6.
- if you have high levels of calcium in your blood (hypercalcemia)
- if you have excessive levels of calcium in your urine (hypercalciuria)
- if you have an overactive parathyroid gland (hyperparathyroidism)
- if you have multiple myeloma (bone marrow cancer)
- if you have cancer that affects your bones (bone metastases)
- if you have a limb problem (prolonged immobilization) along with hypercalcemia and/or hypercalciuria
- if you have kidney stones (nephrolithiasis)
- if you have calcium deposits in your kidneys (nephrocalcinosis)
- if you have an excess of vitamin D (hypervitaminosis D)
- if you have severe kidney problems
- if you are under 18 years of age.

When should you take extra caution with this medicine?

Contact your doctor or pharmacist before using this medicine if any of the following conditions apply to you:

Prolonged treatment: During long-term treatment, the concentrations of calcium in your blood and urine, as well as the function of your kidneys, should be regularly monitored. This is particularly important if you have a tendency to develop kidney stones. Based on the blood concentrations, the doctor may adjust the dosage or discontinue the treatment.

Concurrent treatment with cardiac glycosides or thiazide diuretics (water pills) for heart problems: In such cases, the concentrations of calcium in your blood and urine, as well as the function of your kidneys, should be regularly monitored, especially if you are elderly. Based on the concentrations in your blood, the doctor may lower the dosage or discontinue the treatment.

Kidney problems: If you have kidney problems, you should use this medicine with special caution, especially if you are also using products containing aluminum. The citric acid in this medicine can increase the absorption of aluminum. The calcium levels in your blood and urine should be monitored. If you have severe kidney problems, use forms of vitamin D other than cholecalciferol.

Additional calcium and vitamin D: Take extra calcium and vitamin D only under medical supervision. Your doctor should regularly monitor the calcium levels in your blood and urine.

Sarcoidosis (an immune system disorder that can affect the liver, lungs, skin, or lymph nodes): Exercise extra caution when taking this medicine if you have sarcoidosis. There is a risk that this medicine may become too potent, resulting in an excess of calcium in the body. The calcium concentrations in your blood and urine should be regularly monitored.

Prolonged immobilization and osteoporosis: In such cases, this medicine should be used with special caution, as it may cause an increase in calcium levels in your blood. If you are using this medicine for osteoporosis, it is recommended to have your blood calcium levels checked before starting treatment.

Children and adolescents under 18 years: This medicine should not be used by children and adolescents under 18 years. Refer to section 2: "When should you not use this medicine?"

Are you taking any other medications?: If you are taking other medications, including Calcium/Vitamin D3, or have recently done so, or if you plan to do so in the near future, please inform your doctor or pharmacist.

Concurrent treatment with digitalis glycosides (cardiac glycosides derived from foxglove) can cause cardiac arrhythmias. Strict medical supervision, including an electrocardiogram and measurement of calcium levels in the blood, is necessary in such cases.

Concurrent administration of diuretics from the thiazide group (also known as water pills) requires regular monitoring of calcium levels in the blood, as thiazides reduce the excretion of calcium in the urine.

The absorption and therefore the effectiveness of certain antibiotics (called tetracyclines) are reduced by simultaneous administration of Calcium/Vitamin D3. These medications should be taken at least 2 hours before or 4-6 hours after taking Calcium/Vitamin D3.

Other medications such as sodium fluoride (used to strengthen tooth enamel or treat osteoporosis) and bisphosphonates (used to treat osteoporosis) are also subject to These medications should be taken at least 3 hours before Calcium/Vitamin D3.

A maximum time interval should be maintained between the administration of colestyramine (a medication for lowering elevated cholesterol levels) or laxatives such as liquid paraffin and the administration of Calcium/Vitamin D3 since vitamin D may not be adequately absorbed otherwise.

Orlistat (used for the treatment of obesity) can reduce the absorption of vitamin D. Take Calcium/Vitamin D3 at least two hours before or after the administration of orlistat.

Simultaneous administration of Calcium/Vitamin D3 and rifampicin (an antibiotic), phenytoin (a medication for the treatment of epilepsy), or barbiturates (hypnotics) can cause a reduced effect of vitamin D.

Simultaneous administration of Calcium/Vitamin D3 and glucocorticoids (e.g., cortisone) can cause a reduced effect of vitamin D and a decreased amount of calcium in the blood.

Additional amounts of calcium and vitamin D should only be given under medical supervision, and frequent monitoring of calcium levels in the blood and urine is necessary.

Calcium can reduce the effectiveness of levothyroxine (used in the treatment of an underactive thyroid). For this reason, levothyroxine should be taken at least 4 hours before or 4 hours after Calcium/Vitamin D3.

The effect of quinolone antibiotics may be reduced when taken concurrently with calcium. Quinolone antibiotics should be taken 2 hours before or 6 hours after taking Calcium/Vitamin D3.

Calcium can reduce the absorption of iron, zinc, and strontium ranelate. Take these medications at least 2 hours before or after taking Calcium/Vitamin D3.

Calcium can decrease the absorption of estramustine (used in chemotherapy). Take this medication at least two hours before or after taking Calcium/Vitamin D3.

Regarding food and drink: Note that oxalic acid (found in spinach and rhubarb, among others) and phytic acid (found in whole grains, among others) can reduce the amount of calcium absorbed in the intestine. You should not use calcium-containing medications 2 hours before or after consuming foods high in oxalic acid or phytic acid.

Pregnancy and breastfeeding:

Pregnancy: If you are pregnant and have a calcium and vitamin D deficiency, you may use this medication.

The daily dose of half a tablet should not be exceeded. During pregnancy, the total daily intake of calcium should not exceed 1500 mg, and the total daily intake of vitamin D3 should not exceed 600 IU (International Units).

During pregnancy, prolonged overdosage of calcium and vitamin D should be avoided, as it can lead to high levels of calcium in the blood and have negative effects on the unborn child.

Breastfeeding: This medication can be used during breastfeeding. If your child is already receiving other products with vitamin D, you should first consult your doctor, as calcium and vitamin D can pass into breast milk.

If you are pregnant, think you might be pregnant, planning to become pregnant, or breastfeeding, please contact your doctor or pharmacist before taking this medication.

Driving and using machinery: This medication has no or negligible influence on your ability to drive or operate machinery. However, an effect is unlikely. Calcium/Vitamin D3 contains aspartame, sorbitol, isomalt, sucrose, sodium, and benzyl alcohol. Aspartame is a source of phenylalanine. It can be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine accumulates because the body cannot remove it properly. This medication contains 119.32 mg of sorbitol in each chewable tablet. It also contains isomalt and sucrose. If your doctor has told you that you cannot tolerate certain sugars, please contact your doctor before taking this medication. It may be harmful to the teeth. This medication contains less than 1 mmol of sodium (23 mg) per chewable tablet, which means it is essentially "sodium-free." This medication contains 0.02 mg of benzyl alcohol in each chewable tablet. Benzyl alcohol can cause allergic reactions.

How to use this medication?

Always use this medication exactly as your doctor or pharmacist has instructed you. If you are unsure about the correct usage, please contact your doctor or pharmacist.

Dosage:

The usual dose is: Adults and elderly: 1 chewable tablet per day (equivalent to 1000 mg of calcium and 880 IU of vitamin D3). Pregnant women: not more than half a chewable tablet per day (equivalent to 500 mg of calcium and 440 IU of vitamin D3). The daily dose of half a tablet should not be exceeded.

Use in children and adolescents under 18 years: This medication should not be used in children and adolescents under 18 years of age. See section 2 "When should you not use this medication?"

Method of administration:

- For oral use.
- Chew the tablets before swallowing. You can take this medication at any time, with or without food.
- The tablet can be divided into equal doses.

Duration of treatment: This medication should be taken for a prolonged period. Ask your doctor how long you should take this medication (see also section 2 "When should you take extra care with this medication?").

Have you taken too much of this medication?

Please contact your doctor or pharmacist immediately if an overdose is suspected. Make sure to have the packaging and any remaining chewable tablets available. An overdose of this medication can cause symptoms such as nausea, vomiting, thirst, excessive urination, dehydration, or constipation.

Did you forget to take this medication?

If you have forgotten to take this medication, take it as soon as you remember unless it is time for your next dose. In that case, take the next dose at the usual time. Do not take a double dose to make up for a missed tablet.

If you stop taking this medication

Consult your doctor if you wish to interrupt or stop the treatment prematurely.

Do you have any other questions about the use of this medication? Please contact your doctor or pharmacist.

Possible Side Effects

Like any medication, this medication can have side effects, although not everyone gets them.

Stop using this medication and immediately contact a doctor if you experience any of the following serious side effects:

Very rare side effects (may occur in less than 1 in 10,000 users): Frequent urination, persistent headache, persistent loss of appetite, nausea or vomiting, unusual tiredness or weakness, along with high calcium levels in your blood and kidney problems, which usually occur after an overdose of calcium (milk-alkali syndrome).

Rare side effects (may occur in less than 1 in 1,000 users): Severe allergic reactions: swelling of the face, lips, tongue, or throat with sudden difficulty breathing and severe rash.

Other reported side effects include:

Sometimes side effects (may occur in less than 1 in 100 users): High levels of calcium in the blood (hypercalcemia) or in the urine (hypercalciuria).

Rare side effects (may occur in less than 1 in 1,000 users): Nausea, vomiting, diarrhea, abdominal pain, constipation, flatulence, bloating. Skin rash, itching, hives.

If you have reduced kidney function, you may have an increased risk of elevated phosphate levels in your blood, increased amount of calcium in your kidneys, and kidney stones.

Reporting side effects: If you experience any side effects, please contact your doctor or pharmacist. This also applies to side effects not mentioned in this leaflet. You can also report side effects to the Dutch Pharmacovigilance Centre Lareb. Website: www.lareb.nl. By reporting side effects, you can help us obtain more information about the safety of this medication.

How to store this medication?

Keep out of sight and reach of children.

Do not use this medication after the expiry date printed on the box or the laminated aluminum foil after the abbreviation "EXP." The expiry date consists of a month and a year. The last day of that month is the expiry date.

For the tablet container: Keep the tablet container tightly closed to protect it from moisture.

For the strips: There are no special storage conditions for this medication.

Do not flush medications down the sink or toilet or throw them into the trash. Ask your pharmacist how to dispose of medications that are no longer needed. When medications are properly disposed of, they are destroyed in an environmentally responsible manner.