

Package leaflet: Information for the user

Calcigran 500 mg/200 IU chewable tablets calcium/cholecalciferol

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

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has 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 Calcigran is and what it is used for
2. What you need to know before you use Calcigran
3. How to use Calcigran
4. Possible side effects
5. How to store Calcigran
6. Contents of the pack and other information

1. What Calcigran is and what it is used for

Calcigran chewable tablets contain calcium and vitamin D₃, both of which are important substances in bone formation. Calcigran is used to prevent and treat calcium and vitamin D deficiency, as well as for the specific treatment of osteoporosis.

2. What you need to know before you use Calcigran

Do not use Calcigran

- if you are allergic to calcium, vitamin D, or any of the other ingredients of this medicine (listed in section 6);
- if you have severe kidney disease.
- if you have high levels of calcium in your blood or urine.
- if you have kidney stones.
- if you have high levels of vitamin D in your blood.

Warnings and precautions

Ask your doctor or pharmacist for advice before taking Calcigran:

- if you are taking this medicine for a long time, especially if you are taking diuretics (used to treat high blood pressure or edema) or cardiac glycosides (used to treat heart problems).
- if you have signs of impaired kidney function or a tendency to develop kidney stones.
- if you have sarcoidosis (a disorder of the immune system that can increase the amount of vitamin D in your body).
- if you have osteoporosis and at the same time you cannot move.
- if you are taking other vitamin D supplements. Supplementation with calcium and vitamin D should be performed under medical supervision.

Other medicines and Calcigran

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

If you are taking tetracyclines (certain types of antibiotics), you must take them at least 2 hours before or 4 to 6 hours after taking Calcigran. Calcium carbonate may interfere with the absorption of co-administered tetracycline preparations.

Medicines containing bisphosphonates should be taken at least 1 hour before Calcigran.

Calcium may reduce the effect of levothyroxine. Therefore, levothyroxine should be taken at least 4 hours before or 4 hours after taking Calcigran.

The effect of quinolone antibiotics may be reduced when taken with calcium. Therefore, quinolone antibiotics should be taken at least 2 hours before or 6 hours after taking Calcigran.

Calcium salts may reduce the absorption of iron, zinc, and strontium ranelate. Therefore, formulations containing iron, zinc or strontium ranelate should be taken 2 hours before or after taking Calcigran.

Other medicines that may affect or be affected by Calcigran:

- thiazide diuretics (used to treat high blood pressure or edema),
- cardiac glycosides (used in heart disease).

Treatment with orlistat (an anti-obesity medicine) may reduce the absorption of fat-soluble vitamins (e.g. vitamin D₃).

If you are taking any of the medicines listed above, your doctor will give you more specific instructions.

Calcigran with food and drink

Calcigran can be taken with or without food and drink.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Calcigran can be used during pregnancy in the case of concomitant calcium and vitamin D deficiency. You should not take more than 2,500 mg of calcium and 4,000 IU of vitamin D daily during pregnancy, as overdose may harm your unborn baby.

Calcigran can be used during breast-feeding. Calcium and vitamin D are excreted in breast milk, which must be accounted for if the baby is receiving supplementary vitamin D.

Driving and using machines

Calcigran is not known to affect your ability to drive or use machines. .

Calcigran contains isomalt and sucrose

Calcigran contains sucrose (0.4 mg per tablet), which may be harmful for teeth. In addition, Calcigran contains isomalt (E953). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Calcigran is essentially sodium-free

This medicine contains less than 1 mmol sodium (23 mg) per tablet, ie it is essentially 'sodium-free'.

3. How to use Calcigran

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Dosage

The recommended dose for adults is one chewable tablet 2 to 3 times a day.

Use in children

The recommended dose for children is one chewable tablet 1-2 times a day.

The tablets may be chewed or sucked.

If you take more Calcigran than you should

If you take more Calcigran than you should, contact your doctor or pharmacist immediately.

If you forget to take Calcicran

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

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

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

Hypersensitivity reactions have been reported with an unknown frequency (frequency cannot be estimated from the available data). If you experience the following symptoms, you should contact your doctor immediately: swelling of the face, tongue, lips (angioedema) or larynx (laryngeal edema).

Uncommon side effects (occurring in up to 1 person in 1,000):

At high doses, an increase in blood calcium (hypercalcaemia) or urinary calcium (hypercalciuria) may occur.

Rare side effects (occurring in up to 1 person in 10,000):

Constipation, indigestion, flatulence, nausea, stomach pain and diarrhoea.

Very rare side effects (occurring in up to 1 person in 10,000):

Pruritus, rash and hives, milk-alkali syndrome (also referred to as the Burnett's syndrome and is usually expressed only after administering a large dose of calcium), the symptoms of which are a frequent need to urinate, persisting headache and loss of appetite, nausea or vomiting, unusual tiredness or fatigue, elevated blood calcium levels and renal damage.

If you have impaired kidney function, you may be at risk of increased blood phosphate levels, kidney stones and increased levels of calcium in your kidneys.

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 www.ravimiamet.ee. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Calcigran

Keep this medicine out of the sight and reach of children.

Do not store at a temperature higher than 30°C. Keep the container tightly sealed in order to protect from moisture.

Do not use this medicine after the expiry date which is stated on the carton and container. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Calcigran contains

- The active substances are:
 - calcium carbonate. One tablet contains 1250 mg of calcium carbonate, equivalent to 500 mg of calcium;
 - colecalciferol (vitamin D₃). One tablet contains 200 IU (5 micrograms) of colecalciferol.
- Other ingredients are sorbitol (E420), povidone, isomalt (E953), orange oil, magnesium stearate, aspartame (E951), fatty acid mono- and diglycerides, alpha tocopherol, sucrose, modified corn starch, medium length triglycerides, sodium ascorbate, and anhydrous colloidal silica.

What Calcigran looks like and contents of the pack

Calcigran is a white, round, convex chewable tablet.

Calcigran is available in a 30, 60, 90, 100 or 120 tablet HDPE plastic bottle and outer carton. Not all pack sizes may be marketed.

Marketing Authorisation Holder

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