Package leaflet: Information for the user

Calcichew-D_3 Apelsin 1000 mg/800 IU chewable tablets
calcium / cholecalciferol (vitamin D_3)

[For medicines available only on prescription:]
Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- 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.

[For medicines available without prescription:]
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 have 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.

[To be completed nationally]

What is in this leaflet

1. What [Invented name] is and what it is used for

[Invented name] are chewable tablets containing calcium and vitamin D_3, which both are important substances in bone formation. [Invented name] is used in the prevention and treatment of calcium and vitamin D deficiency in adults with an identified risk of calcium and vitamin D deficiency, and as a supplement to specific treatment of osteoporosis.

2. What you need to know before you take [Invented name]

Do not take [Invented name]:
- 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 problems
- if you have excessive amounts of calcium in the blood or in the urine.
- if you have kidney stones.
- if you have excessive amounts of vitamin D in the blood.

Warnings and precautions
Talk to your doctor or pharmacist before taking [Invented name]

- if you are on long-term treatment, especially if you also take diuretics (used in treatment of high blood pressure or oedema) or cardiac glycosides (used to treat heart disorders).
- if you have signs of impaired renal function or high tendency of renal stone formation.
- if you have sarcoidosis (an immune system disorder which may cause increased levels of vitamin D in the body).
- if you have osteoporosis and at the same time are unable to move around.
- if you take other products containing vitamin D. Additional doses of calcium and vitamin D should be taken under close medical supervision.

Children and adolescents
[Invented name] is not intended for use in children and adolescents.

Other medicines and [Invented name]
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

If you also take tetracyclines (a type of antibiotics), you should take these at least 2 hours before or 4-6 hours after intake of [Invented name]. Calcium carbonate may interfere with the absorption of tetracycline preparations if taken at the same time.

Medicines containing bisphosphonates (used to treat osteoporosis) should be taken at least one hour before intake of [Invented name].

Calcium can reduce the effect of levothyroxine (used to treat thyroid deficiency). For this reason, levothyroxine should be taken at least four hours before or four hours after [Invented name].

The effect of quinolone antibiotics may be reduced if taken at the same time as calcium. Take quinolone antibiotics two hours before or six hours after taking [Invented name].

Calcium salts may decrease the absorption of iron, zinc and strontium ranelate. Consequently, iron, zinc or strontium ranelate preparations should be taken at least two hours before or after [Invented name].

Other medicines that may influence or be influenced by [Invented name] are:
- tiazide diuretics (used in treatment of high blood pressure or oedema)
- cardiac glycosides (used to treat heart disorders)

Orlistat (used to treat obesity) may disturb the absorption of fat-soluble vitamins, e.g. vitamin D_3.

If you are taking any of the above-mentioned medicines, your doctor will give you further instructions.

[Invented name] with food and drink
[Invented name] 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.

If you are pregnant, you may use [Invented name] in case of a calcium and vitamin D deficiency. During pregnancy you should not take more than 2500 mg calcium and 4000 IU vitamin D per day, as overdoses may harm the unborn child.

[Invented name] can be used during breastfeeding. Calcium and vitamin D_3 pass into breast milk. This should be considered when giving additional vitamin D to the child.

Driving and using machines
[Invented name] has no known influence on the ability to drive and use machines.

[Invented name] contains isomalt and sucrose
[Invented name] contains sucrose (1.5 mg), which may be harmful to the teeth. The tablet also 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.

[Invented name] is essentially sodium-free
This medicine contains less than 23 mg sodium per tablet, that is to say essentially 'sodium-free'.

3. How to take [Invented name]

[For medicines available on prescription only:]
Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

[For medicines available without prescription:]
Always take 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 is one tablet once daily. The tablet may be chewed or sucked.

Use in children and adolescents
[Invented name] is not intended for use in children and adolescents.

If you take more [Invented name] than you should

If you may have taken more [Invented name] than you should, talk to your doctor or pharmacist immediately.

If you forget to take [Invented name]

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

If you have any further questions on the use of this medicine, 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 occurred with unknown frequency (cannot be estimated from the available data). If you experience the following symptoms, you should immediately contact a doctor. Swelling of the face, tongue, lips (angioedema) or swelling of the throat (laryngeal oedema).

Uncommon side effects (may affect up to 1 in 100 people)
Excessive amounts of calcium in the blood (hypercalcaemia) or in the urine (hypercalciuria) may occur with large doses.

Rare side effects (may affect up to 1 in 1 000 people)
Constipation, dyspepsia, flatulence, nausea, gastric pain, diarrhoea.

Very rare side effects (may affect up to 1 in 10 000 people)
Itching, rash and hives. Milk-alkali syndrome (also called Burnett's syndrome-and usually only seen when excessive amounts of calcium have been ingested), symptoms are frequent urge to urinate, headache, loss of

appetite, nausea or vomiting, unusual tiredness or weakness, along with elevated levels of calcium in the blood and kidney impairment.

If you have impaired renal function, you may be at risk of increased amounts of phoshate in the blood, kidney stone formation and increased amounts of calcium in the 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 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 [Invented name]

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

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

Plastic bottle: Do not store above 30°C. Store in the original container in order to protect from light. Keep the container tightly closed in order to protect from moisture.

Blister: Do not store above 25°C. Store in the original package in order to protect from moisture. Keep blister in the outer carton in order to protect from light.

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

6. Contents of the pack and other information

What [Invented name] contains
The active substances in one tablet are:
- calcium carbonate 2500 mg (equivalent to 1000 mg calcium)
- cholecalciferol (vitamin D3) 800 IU (20 microgram)

- The other ingredients are xylitol (E967), povidone, isomalt (E953), flavouring (orange), magnesium stearate, sucralose (E955), mono-and diglycerides of fatty acids, all-rac-alpha-tocopherol, sucrose, modified maize starch, medium chain triglycerides, sodium ascorbate and anhydrous colloidal silica.

What [Invented name] looks like and contents of the pack
[Invented name] are white, round chewable tablets. May have small specks.

Pack sizes:
Plastic bottle with HDPE screw cap: 15, 30, 40, 60 and 90 tablets
Blister: 7, 14, 28, 50x1 (unit dose), 56, 84, 112, 140 and 168 tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation holder:

[To be completed nationally]

Manufacturers:

[To be completed nationally]

This medicinal product is authorised in the Member States of the EEA under the following names:
[To be completed nationally]

This leaflet was last revised in 2025-12-19

Other sources of information

Detailed information on this medicine is available on the web site of {name of MS Agency (link)}.