

Package leaflet: Information for the user

Calcichew-D₃ Mite Apelsin 500 mg/200 IU chewable tablets
calcium / cholecalciferol (vitamin D₃)

[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 a 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.

What is in this leaflet:

1. What Calcichew-D₃ Mite Apelsin is and what it is used for
2. What you need to know before you take Calcichew-D₃ Mite Apelsin
3. How to take Calcichew-D₃ Mite Apelsin
4. Possible side effects
5. How to store Calcichew-D₃ Mite Apelsin
6. Contents of the pack and other information

1. What Calcichew-D₃ Mite Apelsin is and what it is used for

Calcichew-D₃ Mite Apelsin are chewable tablets containing calcium and vitamin D₃, which both are important substances in bone formation. Calcichew-D₃ Mite Apelsin is used in the prevention and treatment of calcium and vitamin D deficiency, and as a supplement to specific treatment of osteoporosis.

2. What you need to know before you take Calcichew-D₃ Mite Apelsin

Do not take Calcichew-D₃ Mite Apelsin

- 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 Calcichew-D₃ Mite Apelsin

- if you are on long-term treatment, especially if you also take diuretics (used in the 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 that may increase vitamin D levels 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.

Other medicines and Calcichew-D₃ Mite Apelsin

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 Calcichew-D₃ Mite Apelsin. Calcium carbonate may interfere with the absorption of tetracycline preparations if taken at the same time.

Medicines containing bisphosphonates should be taken at least one hour before intake of Calcichew-D₃ Mite Apelsin.

Calcium can reduce the effect of levothyroxine. For this reason, levothyroxine should be taken at least four hours before or four hours after Calcichew-D₃ Mite Apelsin.

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 Calcichew-D₃ Mite Apelsin.

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 Calcichew-D₃ Mite Apelsin.

- Other medicines that may influence or be influenced by Calcichew-D₃ Mite Apelsin are: thiazide 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 D₃.

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

Calcichew-D₃ Mite Apelsin with food and drink

Calcichew-D₃ Mite Apelsin 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 Calcichew-D₃ Mite Apelsin 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.

Calcichew-D₃ Mite Apelsin can be used during breast-feeding. Calcium and vitamin D₃ pass into breast milk. This should be considered when giving additional vitamin D to your child.

Driving and using machines

Calcichew-D₃ Mite Apelsin has no known influence on the ability to drive and use machines.

Calcichew-D₃ Mite Apelsin contains isomalt and sucrose

Calcichew-D₃ Mite Apelsin contains sucrose (0.4 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.

Calcichew-D₃ Mite Apelsin 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 Calcichew-D₃ Mite Apelsin

[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 for adults is one tablet 1-3 times per day.

Use in children

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

The tablets can be chewed or sucked.

If you take more Calcichew-D₃ Mite Apelsin than you should

If you may have taken more Calcichew-D₃ Mite Apelsin than you should, talk to your doctor or pharmacist immediately.

If you forget to take Calcichew-D₃ Mite Apelsin

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 1000 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 phosphate 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 Calcichew-D₃ Mite Apelsin

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. Keep the container tightly closed in order to protect from moisture. . Store in the original container to protect from light. Shelf life after opening is 6 months.

Blister: Do not store above 25°C. Store in the original package in order to protect from moisture. Keep the blister in the outer carton 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 Calcichew-D₃ Mite Apelsin contains

The active substances in one tablet are:

- calcium carbonate 1250 mg (equivalent to 500 mg calcium)
- cholecalciferol (vitamin D₃) 200 IU (5 microgram)

The other ingredients are:

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

What Calcichew-D₃ Mite Apelsin looks like and contents of the pack

Calcichew-D₃ Mite Apelsin are white, round chewable tablets.

Pack sizes:

Plastic bottle with HDPE screw cap: 20, 30, 50, 60, 90, 100, 120, 168 and 180 tablets

Blisters: 20, 30, 50, 60, 90, 100, 120, 168 and 180 tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation holder:

[To be completed nationally]

Manufacturers:

Tablets packed in plastic bottles:

Asker Contract Manufacturing AS

Drammensveien 852

NO-1383 Asker, Norway

Tablets packed in blister:

Tjoapack Netherlands B.V.

Nieuwe Donk 9,

4879 AC Etten-Leur, The Netherlands

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

Belgium: Steovit D₃sinaasappel

Finland: Calcichew D₃ appelsiini 500 mg/5 mikrog purutabletti

France: Orocal Vitamine D₃ 500 mg/200 U.I.

Luxembourg: Steovit D₃ orange

Sweden: Calcichew-D₃ Mite Apelsin

This leaflet was last revised

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Other sources of information

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