

Package leaflet: Information for the user

Calcichew-D₃ Extra 500 mg/1000 IU chewable tablets calcium/cholecalciferol (vitamin D₃)

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

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

Calcichew-D₃ Extra are chewable tablets containing calcium and vitamin D₃, which both are important substances in bone formation. Calcichew-D₃ Extra 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 Extra

Do not take Calcichew-D₃ Extra:

- if you are allergic to calcium, vitamin D or any of the other ingredients of this medicine (listed in section 6)
- if you have excessive amounts of calcium in the blood or in the urine
- if you have severe kidney problems
- 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 Extra

- 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 impaired renal function.
- 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.

Children and adolescents

Calcichew-D₃ Extra chewable tablets are not intended for use in children and adolescents.

Other medicines and Calcichew-D₃ Extra

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 two hours before or four to six hours after intake of Calcichew-D₃ Extra. 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 Calcichew-D₃ Extra.

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 Calcichew-D₃ Extra.

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 Extra.

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 Extra.

Orlistat (used to treat obesity) may disturb the absorption, and thereby reduce the effect, of fat-soluble vitamins, e.g. vitamin D₃.

Other medicines that may influence or be influenced by Calcichew-D₃ Extra are:

- thiazide diuretics (used in treatment of high blood pressure or oedema)
- cardiac glycosides (used to treat heart disorders)

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

Calcichew-D₃ Extra with food and drink

Calcichew-D₃ Extra 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.

During pregnancy the daily intake should not exceed 1500 mg calcium and 4000 IU vitamin D, as overdoses may have adverse effects on the unborn child. If you are pregnant, you may use Calcichew-D₃ Extra in case of a calcium and vitamin D deficiency.

Calcichew-D₃ Extra 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

No studies on the effects on the ability to drive and use machines have been performed. An effect is however unlikely.

Calcichew-D₃ Extra contains aspartame, sorbitol, isomalt and sucrose

Calcichew-D₃ Extra contains aspartame (E951), a source of phenylalanine. May be harmful for people with phenylketonuria. Calcichew-D₃ Extra contains sorbitol (E420), isomalt (E953), and sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Calcichew-D₃ Extra

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Dosage:

The recommended dose is one tablet once daily. The tablets can be chewed or sucked.

Use in children and adolescents

Calcichew-D₃ Extra is not intended for use in children and adolescents.

If you take more Calcichew-D₃ Extra than you should

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

If you forget to take Calcichew-D₃ Extra

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 any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRAs Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Calcichew-D₃ Extra

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. The expiry date refers to the last day of that month.

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.

Shelf life after first opening of the tablet container is 60 days.

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 Extra contains

The active substances in one tablet are:

- Calcium carbonate 1250 mg (equivalent to 500 mg calcium)
- Cholecalciferol (vitamin D₃) 1000 IU (25 microgram)

The other ingredients are: sorbitol (E420), povidone, isomalt (E953), flavouring (lemon), magnesium stearate, aspartame (E951), mono- and diglycerides of fatty acids, all-rac-alpha-tocopherol, sucrose, modified maize starch, medium-chain triglycerides, sodium ascorbate, colloidal anhydrous silica.

What Calcichew-D₃ Extra looks like and contents of the pack

Calcichew-D₃ Extra are white, round chewable tablets of 16 mm. May have small specks.

Pack sizes:

Tablet container with HDPE screw cap: 30, 60, 90 100 and 120 tablets.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation holder:

Takeda UK Ltd
Building 3
Glory Park
Glory Park Avenue
Wooburn Green
High Wycombe
HP10 0DF

Manufacturers:

Takeda Nycomed AS
Drammensveien 852
P.O.Box 205
NO-1372 Asker
Norway

or

Takeda Pharma AS
55B Jaama Street,
63308 Polva
Estonia

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

Belgium:	Steovit D3 citroen 500 mg/1000 I.E. kauwtabletten
Czech Republic:	Calcichew D3 Lemon 1000 IU žvýkací tablety
France:	CALEGOM VITAMINE D3 500mg/1000UI comprimé à croquer
Greece:	Calcioral D3® Extra 500 mg + 25 µg (1000 IU) μασώμενο δισκίο
Hungary:	Calcichew-D3 500 mg/1000 NE rágótabletta
Ireland:	Calcichew D3 Extra Chewable Tablets
Luxembourg:	Steovit D3 citron 500 mg/1000 UI comprimé à croquer
Netherlands:	Calci-Chew D3 500 mg/1000 I.E. citroen kauwtabletten
Slovakia:	Calcichew D3 Citrón 500mg/1000 IU žuvacie tablety
Spain:	Mastical D sabor limón 500mg/1000 UI comprimidos masticables
Sweden:	Calcichew-D3 Citron 500 mg/1000 IE tuggtabletter

This leaflet was last revised in 04/ 2015.