

Package leaflet: Information for the user

Calcichew-D₃ Forte Double Strength 1000 mg/800 IU chewable tablets calcium/colecalciferol (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 the leaflet or as your doctor or pharmacist have told 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.

What is in this leaflet

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1. What Calcichew-D₃ Forte Double Strength is and what it is used for

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

2. What you need to know before you take Calcichew-D₃ Forte Double Strength

Do not take Calcichew-D₃ Forte Double Strength:

- 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 Forte Double Strength

- 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

Calcichew-D₃ Forte Double Strength chewable tablets are not intended for use in children and adolescents.

Other medicines and Calcichew D₃ Forte Double Strength

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 Forte Double Strength. 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 Forte Double Strength.

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 Forte Double Strength.

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 Forte Double Strength.

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 Forte Double Strength.

Other medicines that may influence or be influenced by Calcichew-D₃ Forte Double Strength 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 Forte Double Strength with food and drink

Calcichew-D₃ Forte Double Strength 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 Forte Double Strength 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 Forte Double Strength can be used during breastfeeding. Calcium and vitamin D₃ pass into breast milk. This should be considered when giving additional vitamin D to the child.

Driving and using machines

Calcichew-D₃ Forte Double Strength has no known influence on the ability to drive and use machines.

Calcichew-D₃ Forte Double Strength contains isomalt and sucrose

Calcichew-D₃ Forte Double Strength contains **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. May be harmful to the teeth.

3. How to take Calcichew-D₃ Forte Double Strength

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 tablet may be chewed or sucked.

Use in children and adolescents

Calcichew-D₃ Forte Double Strength are not intended for use in children and adolescents.

If you take more Calcichew-D₃ Forte Double Strength than you should

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

If you forget to take Calcichew-D₃ Forte Double Strength

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 (hypercalcemia) or in the urine (hypercalcuria) 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 phosphate in the blood, renal stone formation and increased amounts of calcium in the kidneys.

Reporting of side effects

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly to HPRA 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 Forte Double Strength

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.

Tablet container: 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 Calcichew-D₃ Forte Double Strength contains

The active substances in one tablet are:

- calcium carbonate 2500 mg (equivalent to 1000 mg calcium)
- colecalfiferol (vitamin D₃) 800 IU (20 microgram)

The other ingredients are xylitol (E967), povidone, isomalt (E953), flavouring (lemon), 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 (*see also end of Section 2 "Important information about some of the ingredients of Calcichew-D₃ Forte Double Strength"*).

What Calcichew-D₃ Forte Double Strength looks like and contents of the pack

Calcichew-D₃ Forte Double Strength are white, round chewable tablets. May have small specks.

Pack sizes:

Tablet container with HDPE screw cap: 15, 30, 40, 60 and 90 tablets

Blister: 7, 14, 28, 50 x 1 (unit dose), 56, 84, 112, 140 and 168 tablets

Not all pack sizes may be marketed.

Marketing Authorisation holder:

Takeda Product Ireland Ltd
First Floor
3013 Lake Drive
Citywest Business Campus
Dublin 24
Ireland

Manufacturer:

Tablets packed in containers:

Takeda AS
Drammensveien 852
NO-1383 Asker
Norway

or

Takeda Pharma AS
55B Jaama Street,
63308 Polva
Estonia

Tablets packed in blister:

Tjoapack Netherlands B.V.
Nieuwe Donk 9,
4879 AC Etten-Leur, The Netherlands

Or

Delpharm Novara S.r.L.
Via Crosa 86
28065 Cerano (No)
Italy

or

Takeda GmbH – Betriebsstätte Oranienburg
Lehnitzstrasse 70-98
16515 Oranienburg, Germany

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

Austria: Cal-D-or 1000 mg/800 I.E. – Kautabletten
Belgium: Steovit Forte citroen 1000 mg/800 I.E. kauwtabletten
Czech Republic: Calcichew D3 Lemon 800 IU žvýkáci tablety
Germany: Calcimagon-D3 uno
Greece: Calcioral D₃[®] 1000 mg + 20 µg (800 IU) μασώμενο δισκίο
Hungary: Calcichew-D3 1000 mg/800 NE rágótabletta
Ireland: Calcichew-D3 Forte Double Strength 1000 mg / 800 IU Chewable Tablets
Lithuania: Calcigran Forte 1000 mg / 800 TV kramtomosios tabletės
Luxembourg: Steovit Forte citron 1000 mg/800 U.I. comprimés à croquer
Netherlands: Calci-Chew D₃ 1000 mg/800 I.E., kauwtabletten
Norway: Calcigran Forte 1000 mg/800 IE tyggetabletter
Slovakia: Calcichew-D3 Citron 1000 mg/800 IU
Spain: Mastical D Unidia 1000 mg/800 IU comprimidos masticables
Sweden: Calcichew-D₃ Citron 1000 mg/800 IE tuggtablett
UK: Calcichew-D₃ 1000mg/800IU Once Daily Chewable tablets

This leaflet was last revised in 05/2018.

Calcichew-D₃ Forte Double Strength are a combination of calcium and vitamin D designed to keep bones healthy. Calcium is an essential component of bones while vitamin D plays an important role in the absorption of calcium from food.

Requirements for calcium increase with age and, although many people obtain enough calcium from their diet, some people may require a supplement in order that their body has all the calcium it needs to maintain healthy bones. Vitamin D is produced largely from the action of sunlight. Certain foodstuffs do contain vitamin D in reasonable amounts but it is not always possible to obtain all the vitamin D you need from your diet. People who do not get out and about, for instance those who are housebound or people living in nursing and residential homes, may not receive all the vitamin D they need.

People with diets and lifestyles that mean they will obtain less than the recommended intake of calcium and vitamin D are at risk of weakened bones. Prolonged lack of adequate calcium and vitamin D intake can lead to the development of osteoporosis, a condition where bones become weak to a level that minimal trauma (for example, a fall) can result in a fracture, most typically at the hip, spine or wrist.

Calcichew-D₃ Forte Double Strength has been designed to give people whose intakes of Calcium and vitamin D are low a boost to the recommended amounts.

Maintaining healthy bones and helping to avoid osteoporosis is an important issue for many people.

There are many ways that people can help themselves: regular exercise, a balanced diet with an adequate intake of calcium and vitamin D and, for some people, advice on how to prevent falls which may lead to fracture.

The Irish Osteoporosis Society (IOS) is a national charity dedicated to reducing the incidence of Osteoporosis and promoting bone health. The IOS offers information and support to people with osteoporosis, their families and everyone at risk from the disease.

If you are concerned about osteoporosis, please contact the Irish Osteoporosis Society, 114 Pembroke Road, Garden Level, Ballsbridge, Dublin 4. Tel: 1890 252 751, Fax: +353 (0)1 668 0098, email: info@irishosteoporosis.ie.