

Package leaflet: Information for the user
Calcichew-D₃ Forte 500 mg/400 IU film-coated 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 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 Forte film-coated tablets are and what they are used for
2. What you need to know before you take Calcichew-D₃ Forte film-coated tablets
3. How to take Calcichew-D₃ Forte film-coated tablets
4. Possible side effects
5. How to store Calcichew-D₃ Forte film-coated tablets
6. Contents of the pack and other information

1. What Calcichew-D₃ Forte film-coated tablets is and what it is used for

Calcichew-D₃ Forte film-coated tablets are film-coated tablets containing calcium and vitamin D₃, which both are important substances in bone formation. Calcichew-D₃ Forte film-coated tablets are 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 film-coated tablets

Do not take Calcichew-D₃ Forte film-coated tablets:

- 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.
- if you are allergic to calcium, vitamin D, or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking Calcichew-D₃ Forte film-coated tablets

- 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). Please consult your doctor.
- if you have sarcoidosis (an immune system disorder which may cause increased levels of vitamin D in the body). Please consult your doctor.
- if you have osteoporosis and are unable to move around. Please consult your doctor.
- 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 Forte film-coated tablets

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

Calcium carbonate may interfere with the absorption of tetracyclines (a type of antibiotics) if taken at the same time. For this reason, tetracycline preparations should be taken at least 2 hours before or 4-6 hours after intake of Calcichew-D₃ Forte film-coated tablets.

Medicines containing bisphosphonates (used to treat osteoporosis) should be taken at least one hour before intake of Calcichew-D₃ Forte film-coated tablets.

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 film-coated tablets.

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 film-coated tablets

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 film-coated tablets.

Other medicines that may influence or be influenced by Calcichew-D₃ Forte film-coated tablets are: thiazide diuretics (used in treatment of high blood pressure and oedema) and cardiac glycosides (used to treat heart disorders).

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

Calcichew-D₃ Forte film-coated tablets with food and drink

Calcichew-D₃ Forte film-coated tablets 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 before taking this medicine.

Pregnancy

During pregnancy the daily intake should not exceed 1500 mg calcium and 600 IU vitamin D. Ask your doctor or pharmacist for advice. Calcichew-D₃ Forte film-coated tablets can be used during pregnancy, in case of calcium and vitamin D deficiency.

Breast-feeding

Calcichew-D₃ Forte film-coated tablets 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

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

Calcichew-D₃ Forte film-coated tablets contains sorbitol and sucrose.

Calcichew-D₃ Forte film-coated tablets contains sorbitol 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 film-coated tablets

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 twice daily. The tablet may be swallowed or chewed.

If you take more Calcichew-D₃ Forte film-coated tablets than you should

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

If you forget to take Calcichew-D₃ Forte film-coated tablets

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

4. Possible side effects

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

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

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

Very rare side effects (may affect up to 1 in 10,000 people): itching and rash and dyspepsia. 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.

Frequency not known (cannot be estimated from the available data): Hypersensitivity reactions such as swelling of the face, tongue, lips (angioedema) or swelling of the throat (laryngeal oedema).

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, pharmacist or nurse. 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 film-coated tablets

Do not store above 25°C. Keep the container tightly closed in order to protect from moisture.

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 throw any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Calcichew-D₃ Forte film-coated tablets contains

- The active substances are 500 mg calcium (as calcium carbonate) and 400 IU vitamin D₃ (equivalent to 10 micrograms cholecalciferol).
- The other ingredients are
- tablet core: sorbitol E420, mannitol, acesulfame potassium, flavouring (lemon), croscarmellose sodium, microcrystalline cellulose, magnesium stearate, maltodextrin, tocopherol-rich extract, all-rac-alpha-tocopherol, sucrose, modified maize starch, medium chain triglycerides, sodium ascorbate and anhydrous colloidal silica
- film-coating: talc, hypromellose, propylene glycol.

What Calcichew-D₃ Forte film-coated tablets looks like and contents of the pack

Calcichew-D₃ Forte film-coated tablets are white/off white, oval film-coated tablets.

Pack sizes:

20, 30, 50, 60, 90, 100, 120, 180 and 250 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder

Takeda UK Limited
Building 3
Glory Park
Glory Park Avenue
Wooburn Green
BUCKS
HP10 0DF
UK

Manufacturer

Takeda Pharma A/S
Langebjerg 1
DK-4000 Roskilde
Denmark

or

Takeda Pharma AS
Jaama 55B
63308 Põlva
Estonia

or

Takeda GmbH
Lehnitzstr. 70-98
DE-16515 Oranienburg
Germany

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

Austria: Cal-D-or 500 mg/400 I.E. - Filmtabletten

Belgium: Steovit D3 500 mg/400 I.E., filmomhulde tabletten

Denmark: Calcichew-D3 Forte Flex

Estonia: Calcigran Forte 500 mg/400 IU film-coated tablets Flex

Finland: Calcichew D₃ Forte sitruuna 500 mg/10 mikrog – kalvopäällysteinen tabletti

Greece: Calcioral D₃[®], 500 mg + 10 µg (400 IU), επικαλυμμένο με λεπτό υμένιο δισκίο

Ireland: Calcichew-D₃ Forte 500 mg/400 IU Film-coated Tablets

Latvia: Calcigran Forte Flex 500 mg / 400 IU SV apvalkotās tabletes Lithuania: Calcigran Forte Flex 500 mg / 400 TV plėvele dengtos tabletės

Luxembourg: Steovit D3 500 mg/400 U.I., comprimé pelliculé

Netherlands: Calci-Chew D3 FLEX 500 mg/400 I.E.

Norway: Calcigran Forte 500 mg/400 IE tabletter, filmdrasjerte

Poland: Orocal D₃ Tab

Sweden: Calci-D₃ Citron 500 mg/400 IE filmdragerad tablett

UK: Calcichew-D₃ 500 mg/400IU Caplets

This leaflet was last revised in 10/2015

<Detailed information on this medicine is available on the web site of MA/Agency