

Package leaflet: Information for the user

Calcichew-D₃[®] Forte 500 mg/400 IU Chewable Tablets

(calcium/colecalciferol)

Read all of this leaflet carefully 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.
- * You must talk to a doctor if you do not feel better or if you feel worse after two weeks.
- * 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.

In this leaflet:

- 1 What Calcichew- D₃ Forte is and what it is used for
- 2 What you need to know before you take Calcichew- D₃ Forte
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1 What Calcichew- D₃ Forte is and what it is used for

Calcichew- D₃ Forte Chewable Tablets are lemon flavoured chewable tablets containing calcium and vitamin D₃ which are both important substances in bone formation. Both are found in the diet and vitamin D is also produced in the skin after exposure to the sun

Calcichew- D₃ Forte is used to treat and prevent vitamin D/calcium deficiency, which may occur when your diet or lifestyle does not provide enough, or when body requirements are increased. This medicine may also be prescribed or recommended for certain bone conditions, for example osteoporosis, or during pregnancy.

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

Do not take Calcichew- D₃ Forte Chewable Tablets if you:

- * are allergic to calcium, vitamin D, or any of the other ingredients of this medicine (listed in section 6)
- * have severe kidney problems
- * have a condition that causes excessive amounts of calcium in your blood or urine (hypercalcaemia or hypercalciuria) e.g.
 - renal (kidney failure)
 - cancer that has affected your bones
- * have excessive amounts of vitamin D in your blood
- * have kidney stones.

Warnings and precautions

Talk to your doctor or pharmacist before taking Calcichew- D₃ Forte:

- * if you have **osteoporosis** (brittle bones) and are also unable to move around
- * if you are on long term treatment, especially if you are taking medicines for a **heart disorder** (cardiac glycosides), or **diuretics** (used in the treatment of high blood pressure or oedema)
- * if you have signs of **impaired kidney function** or a high tendency to **kidney stone** (calculus) formation
- * if you have **cancer** or any other conditions that may have affected your bones
- * if you have **sarcoidosis** (an immune system disorder which may cause increased levels of vitamin D in the body).

If you have any of the following conditions your serum calcium or phosphate levels, or urinary calcium excretion must be monitored. Calcichew should be taken under close medical supervision.

- * **sarcoidosis** (an immune system disorder which may affect your liver, lungs, skin or lymph nodes)
- * **kidney problems**
- * you are on **long-term** treatment with Calcichew
- * you are already taking **additional doses** of **calcium** or **vitamin D**.

If you have increased calcium levels in the blood or develop signs of kidney problems, the dose of Calcichew-D₃ Forte should be reduced or the treatment discontinued.

Other medicines and Calcichew- D₃ Forte

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

In particular, the following medicines may interact with Calcichew- D₃ Forte chewable tablets:

- * **thiazide diuretics** (water tablets); your serum calcium levels should be monitored regularly.
- * **cardiac glycosides** (heart medicines); you should be monitored by electrocardiogram (ECG) and your serum calcium levels measured.
- * **tetracycline antibiotics**; these should be taken at least two hours before, or four to six hours afterwards. Calcium carbonate may interfere with the absorption of tetracycline preparations if taken at the same time.
- * **levothyroxine (hormone used to treat thyroid deficiency)**; these should be taken at least four hours before or after taking Calcichew- D₃ Forte.
- * **quinolone antibiotics (ciprofloxacin, lomefloxacin, norfloxacin, sparfloxacin)**: the effect of these medicines 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.
- * **bisphosphonates**; should be taken at least one hour before Calcichew- D₃ Forte.
- * 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.
- * **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.

Taking Calcichew- D₃ Forte with food and drink

Calcichew- D₃ Forte can be taken with or without food and drink.

Pregnancy and breastfeeding

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 if you are pregnant or breast-feeding before taking Calcichew-D₃ Forte.

If you are pregnant, you may use Calcichew- D₃ Forte 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 can be used during breast-feeding. 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 has no known influence on the ability to drive or use machines.

Calcichew- D₃ Forte contains isomalt and sucrose.

Calcichew- D₃ Forte contains isomalt (E953) and sucrose (E420): if you have been told by your doctor that you have an intolerance to some sugars talk to your doctor before taking this medicine. May be harmful to teeth.

3 How to take Calcichew- D₃ Forte

Always take Calcichew- D₃ Forte Tablets exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Dosage

The recommended dose is two tablets a day, preferably one tablet in the morning and one tablet in the evening. The tablet may be chewed or sucked.

Children:

Calcichew- D₃ Forte Tablets are **not** recommended for use in children

If you take more than you should

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

If you forget to take Calcichew- D₃ Forte Chewable Tablets

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.

Package leaflet: Information for the user (continued)**Calcichew-D₃[®] Forte 500 mg/400 IU Chewable Tablets**

(calcium/colecalciferol)

4 Possible side effects

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

Stop taking your medicine and see a doctor immediately if you experience:

- * 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.

Side effects include:

Uncommon side-effects (may affect less than 1 in 100 people):

- * **excessive amounts of calcium in your blood** (hypercalcaemia) or **in your urine** (hypercalcuria) may occur with large doses

Rare side-effects (may affect less than 1 in 1,000 people):

- * nausea
- * stomach ache
- * constipation
- * heartburn (dyspepsia)
- * diarrhoea
- * wind (flatulence)
- * rash
- * hives
- * itching

Very rare side-effects (may affect less than 1 in 10,000 people):

- * 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.

Side effects with 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.

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

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

Store in the original package. Keep container tightly closed to protect from moisture. Do not store above 30°C

Do not use this medicine after the expiry date which is stated on the label after EXP. The expiry date refers to the last date of that month. If the tablets have changed shape or colour do not use.

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 Chewable Tablets contain

The active ingredients in each tablet are:

- * 1250mg calcium carbonate (equivalent to 500mg calcium)
- * 400IU colecalciferol (equivalent to 10 micrograms vitamin D₃)

The other ingredients are: xylitol (E967), povidone, isomalt (E953), fatty acid mono - and di-glycerides, magnesium stearate, lemon flavour, sucralose (E955), sucrose, tocopherol, modified maize starch, medium-chain triglycerides, sodium ascorbate and anhydrous colloidal silica. (see also end of section 2 "Calcichew-D₃ Forte contains isomalt and sucrose").

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

The tablets are round, white, uncoated, convex and lemon flavoured: they may have small specks.

The tablets are packed in white, plastic bottles of 60 tablets.

Parallel Product Authorisation Holder:

LTT Pharma Limited, Unit 18 Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE.

Re-packaged by:

Lexon (UK) Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE.

Manufacturer:

This medicine is manufactured by Takeda AS, Drammensveien 852, N-1385 Asker, Norway.

Calcichew is a registered trademark of Takeda AS.

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Blind or partially sighted?

Is this leaflet hard to see or read?

Phone LTT Pharma Limited, Tel: +44 (0) 1527 505414 for help.

Additional Information

Calcichew- D₃ Forte 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 have 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.