

PATIENT INFORMATION LEAFLET

CALCICHEW*-D₃ FORTE CHEWABLE TABLETS

calcium carbonate / colecalciferol
equivalent to 500mg Calcium / 400IU colecalciferol

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription. However, you still need to take Calcichew-D₃ Forte Chewable Tablets carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve after two weeks.
- If any of these side-effects become serious, or if you notice any side effects not listed in this leaflet, please talk to your doctor or pharmacist.

In this leaflet:

1. What Calcichew-D₃ Forte Tablets are and what they are used for
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1. WHAT CALCICHEW- D₃ FORTE ARE AND WHAT THEY ARE USED FOR

Calcichew- D₃ Forte are lemon flavoured chewable tablets. They contain the active ingredients:

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

Both calcium and vitamin D are found in the diet and vitamin D is also produced in the skin after exposure to the sun.

Calcichew- D₃ Forte Chewable Tablets may be prescribed by doctors or recommended by pharmacists to treat and prevent vitamin D/calcium deficiency, or when the 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 in pregnancy.

2. BEFORE YOU TAKE CALCICHEW- D₃ FORTE

Do not take Calcichew- D₃ Forte if you:

- are allergic (hypersensitive) to any of the ingredients (*see end of Section 2 and Section 6*)
- are allergic (hypersensitive) to soya or peanuts
- have a condition causing high levels of calcium in your blood or urine (hypercalcaemia or hypercalciuria) e.g.
 - renal (kidney failure)

- cancer that has affected your bones
- have high levels of vitamin D in your blood
- have kidney stones.

Take special care with Calcichew- D₃ Forte :

If any of the following applies to you, please tell your doctor:

- **phenylketonuria** (a deficiency in the enzyme which breaks down phenylalanine) as these tablets contain aspartame, a source of phenylalanine
- **brittle bones** (osteoporosis) as a result of being immobile
- taking medicines for your **heart**, or **diuretics**
- a high tendency to **kidney stone** (calculus) formation
- **cancer** or any other conditions that may have affected your bones.

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**. Calcichew should be taken under close medical supervision

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.

Taking other medicines

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

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

- **diuretics** (water tablets); your serum calcium levels should be monitored regularly.
- **heart medicines** (cardiac glycosides); you should be monitored by electrocardiogram and your serum calcium levels measured.
- **corticosteroids** (e.g. prednisolone, dexamethasone); your dose of Calcichew- D₃ Forte may need to be increased
- **laxatives** (such as paraffin oil) or a cholesterol-lowering drug called **colestyramine**.
- **tetracycline antibiotics**; these should be taken at least two hours before, or four to six hours afterwards.
- **Hormones (levothyroxine)**; these should be taken at least four hours before, or afterwards.
- **Anti-infectives (Quinolones: Ciprofloxacin, lomefloxacin, norfloxacin, sparfloxacin)**: please speak with your doctor.
- **fluoride, or bisphosphonates**; Calcichew- D₃ Forte should be taken at least three hours afterwards.

Taking Calcichew- D₃ Forte with food and drink

Calcichew- D₃ Forte should not be taken within 2 hours of eating foods rich in oxalic acid (found in spinach and rhubarb) or phytic acid (found in whole cereals).

Pregnancy and breastfeeding

Ask your doctor or pharmacist for advice if you are pregnant or breast-feeding before taking Calcichew- D₃ Forte .

Driving and using machines

Calcichew- D₃ Forte has no known effect on your ability to drive or use machines.

Important information about some of the ingredients of Calcichew- D₃ Forte

The following are ingredients in this product:

- **Sorbitol, isomalt and sucrose:** if you have been told by your doctor that you have an intolerance to some sugars, talk to your doctor before taking this medicine.
- **Aspartame** contains a source of phenylalanine and may be harmful to people with phenylketonuria (a deficiency in the enzyme which breaks down phenylalanine).
- **Hydrogenated soya bean oil:** if you are allergic to peanut or soya, do not use this medicinal product

3. HOW TO TAKE CALCICHEW- D₃ FORTE

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

Adults and elderly:

Chew or suck the two tablets a day, preferably one tablet in the morning and one in the evening.

Children:

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

If you take more than you should

If you accidentally take more Calcichew- D₃ Forte Chewable Tablets than you should, you may have an increase in your blood calcium levels.

Symptoms of this are: excessive thirst, nausea, vomiting, constipation, abdominal pain, muscle weakness, tiredness, mental disturbances, lack of appetite, bone pain, having to pass more water than usual, kidney problems and, in severe cases, irregular heartbeat.

Very rarely in addition: irritability, continuing headache, lightheadedness, muscle spasms, twitches and tingling sensation.

Do not take any more Calcichew-D₃ Forte and **contact your doctor or emergency department as soon as possible**. Take the packet and any remaining tablets with you.

If you forget to take Calcichew- D₃ Forte

If you forget to take a dose, leave out that dose completely. Take your next dose when it is due. Do not take a double dose to make up for a forgotten dose.

4. POSSIBLE SIDE-EFFECTS

Like all medicines, Calcichew- D₃ Forte can cause side-effects, although not everybody gets them.

Side effects with Calcichew- D₃ Forte may include:

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

- **too much calcium in your blood** (hypercalcaemia) – the symptoms include nausea, vomiting, lack of appetite, constipation, stomach ache, bone pain, extreme thirst, a need to pass more water than usual, muscle weakness, drowsiness and confusion.
- **too much calcium in your urine** (hypercalciuria)

Rare side-effects (affecting less than 1 in 1000 people):

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

Very rare side-effects (affecting less than 1 in 10000 people):

- Milk alkali syndrome –(usually only seen in overdose see “*if you take more than you should*”)

If any of these side-effects become serious, or if you notice any side-effect(s) not listed in this leaflet, please talk to your doctor or pharmacist.

5. HOW TO STORE CALCICHEW-D₃ FORTE

Keep out of the reach and sight of children.

Store in the original package and protect from moisture. Do not store above 30°C

Do not use Calcichew- D₃ Forte Chewable Tablets 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.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Calcichew-D₃ Forte Chewable Tablets contain

The active ingredients in each tablet are:

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

The other ingredients are: sorbitol (E420), povidone, isomalt (E953), fatty acid mono- and di-glycerides, magnesium stearate, lemon flavour, aspartame (E951), sucrose, gelatin, hydrogenated soya bean oil, tocopherol and maize starch (*see also end of Section 2 “Important information about some of the ingredients of Calcichew- D₃ Forte Chewable Tablets”*).

This product is gluten and lactose free.

What Calcichew-D₃ Forte look 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 or 100 tablets.

Marketing Authorisation Holder Shire Pharmaceuticals Ltd, Hampshire International Business Park, Chineham, Basingstoke, Hampshire RG24 8EP, UK.

Manufacturer

Nycomed Pharma AS, Drammensveien 852, N-1385 Asker, Norway.

This leaflet was approved in June 2010

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.

For patients in the UK, the National Osteoporosis Society (NOS) is a national charity dedicated to improving the diagnosis, prevention and treatment of osteoporosis. The NOS offers support to people with osteoporosis and raises awareness of the importance of healthy bones.

If you are concerned about osteoporosis, please contact the National Osteoporosis Society, Camerton, Bath BA2 0PJ. Tel: 01761 471 771, Fax: 01761 471 104 or email:

info@nos.org.uk. For patients in the Republic of Ireland, please contact the Irish Osteoporosis Society, 33 Pearse Street, Dublin 2. Tel/Fax: 01 677 4267, email: info@irishosteoporosis.ie

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