

**PATIENT INFORMATION LEAFLET**  
**Calcichew-D<sub>3</sub> 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.

The name of your medicine is Calcichew-D3 Forte® Chewable Tablets but will be referred to as Calcichew-D3 Forte throughout this leaflet.

**In this leaflet:**

1. What Calcichew-D3 Forte 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** (1250mg 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 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)
- 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**.

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:

- **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 breast-feeding**

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 intolerance to some sugars, talk to your doctor before taking this medicine. May be harmful to teeth.
- **Aspartame** contains a source of phenylalanine and may be harmful to people with phenylketonuria (a deficiency in the enzyme which breaks down phenylalanine).

**3. HOW TO TAKE CALCICHEW- D3 FORTE**

Always take Calcichew- D3 Forte 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 are **not** recommended for use in children **If you take more than you should**

If you accidentally take more Calcichew- D3 Forte 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")

#### **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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517.

Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto: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 out of the sight and reach of children.

Do not use Calcichew- D3 Forte 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.

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

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 contain**

Each tablet contains 1250mg calcium carbonate (equivalent to 500mg calcium) and 400IU colecalciferol (equivalent to 10micrograms Vitamin D3)

**The other ingredients are:** sorbitol (E420), povidone, isomalt (E953), fatty acid mono- and di-glycerides, magnesium stearate, lemon flavour, aspartame (E951), sucrose, tocopherol, 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').

### **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 containing 60 or 100 tablets.

**Manufactured by:** Takeda Nycomed AS, Drammensveien 852, N-1385 Asker, Norway.

### **Procured from within the EU and repackaged by the**

**PPA holder:** B&S Healthcare, Unit 4, Bradfield Road, Ruislip, Middlesex, HA4 ONU, UK

**Calcichew-D3 Forte® Chewable Tablets**

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**PPA No: 1328/209/1**

Leaflet date: 06.08.2014

Calcichew-D3 Forte is a registered trademark of Takeda Pharmaceuticals

### **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.

If you are concerned about osteoporosis, please contact the Irish Osteoporosis Society, 33 Pearse Street, Dublin 2. Tel/Fax: 01 677 4267, email: [info@irishosteoporosis.ie](mailto:info@irishosteoporosis.ie)