

PATIENT INFORMATION LEAFLET

Calcichew* Forte 1000 mg Chewable Tablets calcium carbonate

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.
- You must talk to a doctor if you do not feel better or if you feel worse after two weeks.
- If you get any of the 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 Forte is and what it is used for
2. What you need to know before you take Calcichew Forte
3. How to take Calcichew Forte
4. Possible side-effects
5. How to store Calcichew Forte
6. Contents of the pack and other information

1. What Calcichew Forte is and what it is used for

Calcichew Forte 1000 mg Chewable Tablets are orange flavoured chewable tablets containing the active ingredient calcium. Calcium is found in the diet and is an important substance in bone formation.

Calcichew Forte is used to treat and prevent calcium deficiency which may occur if 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. It may also be given to patients receiving renal dialysis to remove the phosphate from the blood that cannot be removed by dialysis.

2. What you need to know before you take Calcichew Forte

Do not take Calcichew Forte if you:

- are allergic (hypersensitive) to calcium or any of the other ingredients of this medicine (listed in section 6)
- have a condition that causes excess amounts of calcium in your blood or urine (hypercalcaemia or hypercalciuria)
- have kidney stones.

Warnings and precautions

Talk to your doctor or pharmacist before taking Calcichew Forte:

- if you have **osteoporosis (brittle bones)** as a result of being immobile

- 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.

Your serum calcium or phosphate levels, or urinary calcium excretion must be monitored if you have any of the following conditions.

- **kidney** problems
- you are on **long-term** treatment with Calcichew
- you are already taking **additional doses** of **calcium**

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

Other medicines and Calcichew Forte

Tell 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 Forte 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 afterwards.
- **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 500 mg
- **bisphosphonates**; should be taken at least one hour before Calcichew 500 mg.
- 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 Forte

Taking Calcichew Forte with food and drink

For treatment of calcium deficiency or use as an additional osteoporosis therapy, Calcichew Forte can be taken with or without food and drink.

For use as a phosphate binder, Calcichew Forte should be taken just before, during or just after each meal.

Pregnancy, breastfeeding 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 Calcichew Forte.

During pregnancy the daily intake should not exceed 2500 mg calcium (including food and supplementation). If you are pregnant, you may use Calcichew 500 mg in case of a calcium deficiency.

Calcichew Forte can be used during breastfeeding. Calcium passes into breast milk.

Driving and using machines

Calcichew Forte has no known influence on the ability to drive or use machines.

Calcichew Forte contains isomalt

Calcichew Forte contains isomalt (E953): 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 Forte

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Dosage:

The recommended dose is:

For use as an additional osteoporosis therapy:

One tablet daily.

For calcium deficiency:

One tablet daily.

As a phosphate binder (for kidney failure patients on dialysis):

Your doctor will decide how many Calcichew Forte Chewable Tablets you need. The label the pharmacist puts on your medicine will tell you exactly how many tablets to take.

Use in children

The recommended dose for children is one tablet daily.

The tablets can be chewed or sucked.

If you take more than you should

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

If you accidentally take more Calcichew 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.

If you forget to take Calcichew 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.

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 any of the following side effects. These side effects may be a sign of milk-alkali syndrome (also called Burnett's Syndrome) that is reported to occur very rarely (affects less than 1 in 10,000 people):

- 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 may include:

Uncommon side effects (may affect up to 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 up to 1 in 1,000 people):

- nausea
- stomach ache
- constipation
- diarrhoea
- wind (flatulence)
- heartburn (dyspepsia)

Very rare side effects (may affect up to 1 in 10,000 people):

- rash
- hives
- itching

If you are taking Calcichew Forte Chewable Tablets because you are having kidney dialysis, tell your doctor if you notice any white deposits on your skin.

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 via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Calcichew Forte

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

Store in the original package 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 day of that month.

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 to protect the environment.

6. Contents of the pack and other information

What Calcichew Forte Chewable Tablets contain

The active ingredient in each tablet is:

- 2500 mg calcium carbonate (equivalent to 1000mg calcium)

The other ingredients are: xylitol (E967), povidone, isomalt (E953), fatty acid mono- and di-glycerides, magnesium stearate, orange flavour, sucralose (E955) (see also end of Section 2 “*Calcichew Forte contains isomalt*”).

What Calcichew Forte look like and contents of the pack

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

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

Marketing Authorisation Holder

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Manufacturer

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Additional Information

Calcichew Forte contains calcium designed to keep bones healthy. Calcium is an essential component of bones.

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.

People with diets and lifestyles that mean they will obtain less than the recommended intake of calcium are at risk of weakened bones. Prolonged lack of adequate calcium 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 Forte has been designed to give people, whose intake of calcium is 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, for some people, advice on how to prevent falls which may lead to fracture.

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.

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