

Package leaflet: Information for the user
CALCICHEW® 500 mg CHEWABLE TABLETS

calcium

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 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 500 mg is and what it is used for
2. What you need to know before you take Calcichew 500 mg
3. How to take Calcichew 500 mg
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6. Contents of the pack and other information

1. What Calcichew 500 mg is and what it is used for

Calcichew 500 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 500 mg 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 kidney dialysis to remove the phosphate from the blood that cannot be removed by dialysis.

2. What you need to know before you take Calcichew 500 mg

Do not take Calcichew 500 mg Chewable Tablets 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 excessive 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 500 mg:

- 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.

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 500 mg should be reduced or the treatment discontinued.

Other medicines and Calcichew 500 mg

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

In particular, the following medicines may interact with Calcichew 500 mg 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 500 mg.
- **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 500 mg.

If you are taking any of the above-mentioned medicines, your doctor will give you further instructions.

Taking Calcichew 500 mg with food and drink

For treatment of calcium deficiency or use as an additional osteoporosis therapy, Calcichew 500 mg can be taken with or without food and drink.

For use as a phosphate binder, Calcichew 500 mg should be taken just before, during or just after each meal.

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 for advice before taking Calcichew 500 mg.

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 500 mg can be used during breast-feeding. Calcium passes into breast milk.

Driving and using machines

Calcichew 500 mg has no known influence on the ability to drive or use machines.

Calcichew 500 mg contains isomalt

Calcium 500 mg 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 500 mg

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 2 or 3 times a day.

For calcium deficiency: One tablet 2 or 3 times a day.

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

Your doctor will decide how many Calcichew 500 mg 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 2 or 3 times a day.

The tablets can be chewed or sucked.

If you take more than you should

If you have taken more Calcichew 500 mg than you should, talk to your doctor or pharmacist immediately. If you accidentally take more Calcichew 500 mg 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, light-headedness, muscle spasms, twitches and tingling sensation.

If you forget to take Calcichew 500 mg 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** (hypercalciuria) 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 less than 1 in 10,000 people):

- rash
- hives
- itching

If you are taking Calcichew 500 mg 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 to HPR A 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 500 mg

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

Keep the bottle tightly closed in order 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 protect the environment.

6. Contents of the pack and other information

What Calcichew 500 mg Chewable Tablets contain

The active substance is calcium. Each tablet contains 1250 mg calcium carbonate equivalent to 500 mg calcium.

The other ingredients are: xylitol (E967), povidone, isomalt (E953), fatty acid mono- and diglycerides, magnesium stearate, orange flavour, and sucralose (E955) (see also end of Section 2 "Calcichew 500 mg contains isomalt").

What Calcichew 500 mg 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.

Product procured from within the EU, repackaged and distributed by the parallel product authorisation holder who is: PCO Manufacturing, Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath, Ireland.

Manufacturer

Takeda AS/Takeda Nycomed AS, Drammensveien 852, NO-1383 Asker, Norway or Takeda Pharma AS, 55B Jaama Street 63308 Polva, Estonia or Nycomed Danmark ApS, Langebjerg 1, 4000 Roskilde, Denmark

Parallel Product Authorisation Number: PPA 465/156/1
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Additional Information

Calcichew 500 mg 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 500 mg have 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 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 6680098, Email: info@irishosteoporosis.ie

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