

PACKAGE LEAFLET: INFORMATION FOR THE USER

CALCIMONTA

500mg/400IU Chewable tablets

CALCIUM / COLECALCIFEROL (VITAMIN D3)

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

• Keep this leaflet • You may need to read it again • If you have any further questions, ask your doctor or pharmacist • This medicine has been prescribed for you only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •

What is in this leaflet?

1. What Calcimonta Chewable tablets are and what they are used for
2. What you need to know before you take Calcimonta Chewable tablets
3. How to take Calcimonta Chewable tablets
4. Possible side effects
5. How to store Calcimonta Chewable tablets

1. WHAT CALCIMONTA CHEWABLE TABLETS ARE AND WHAT THEY ARE USED FOR

Calcimonta Chewable tablets are tablets containing calcium and vitamin D3, which both are important substances in bone formation. Calcimonta is used in the prevention and treatment of calcium and vitamin D deficiency in the elderly, and as a supplement to specific treatment of osteoporosis.

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

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE CALCIMONTA CHEWABLE TABLETS

Do not take Calcimonta Chewable tablets:

- if you have excessive amounts of calcium in the blood or in the urine.
- if you have severe kidney problems
- if you have kidney stones.
- if you have excessive amounts of vitamin D in the blood.
- if you are allergic to soya or peanut. Calcimonta Chewable tablets contain soya oil.
- if you are allergic to calcium, vitamin D, or any of the other ingredients of this medicine.

Warnings and precautions

Talk to your doctor or pharmacist before taking Calcimonta Chewable tablets

- if you are on long-term treatment, especially if you also take diuretics (used in treatment of high blood pressure or oedema) or cardiac glycosides (used to treat heart disorders). Please consult your doctor.
- if you have sarcoidosis (an immune system disorder which may cause increased levels of vitamin D in the body). Please consult your doctor.
- if you have osteoporosis and are unable to move around. Please consult your doctor.
- if you take other products containing vitamin D. Additional doses of calcium and vitamin D should be taken under close medical supervision.

Other medicines and Calcimonta

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

Calcium carbonate may interfere with the absorption of tetracyclines (a type of antibiotics) if taken at the same time. For this reason, tetracycline preparations should be taken at least 2 hours before or 4-6 hours after intake of Calcimonta.

Medicines containing bisphosphonates (used to treat osteoporosis) should be taken at least one hour before intake of Calcimonta.

Calcium can reduce the effect of levothyroxine (used to treat thyroid deficiency). For this reason, levothyroxine should be taken at least four hours before or four hours after Calcimonta.

The effect of quinolone antibiotics may be reduced if taken at the same time as calcium. Take quinolone antibiotics two hours before or six hours after taking Calcimonta.

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 Calcimonta.

Other medicines that may influence or be influenced by Calcimonta are: thiazide diuretics (used in treatment of high blood pressure and oedema) and cardiac glycosides (used to treat heart disorders).

Orlistat (used to treat obesity) may disturb the absorption of fat-soluble vitamins, e.g. vitamin D3.

Calcimonta with food and drink

Calcimonta can be taken with or without food and drink.

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 before taking this medicine.

Pregnancy

During pregnancy the daily intake should not exceed 1500 mg calcium and 600 IU vitamin D. Ask your doctor or pharmacist for advice. Calcimonta can be used during pregnancy, in case of calcium and vitamin D deficiency.

Breast-feeding

Calcimonta Chewable tablets can be used during breastfeeding. Calcium and vitamin D3 pass into breast milk. This should be considered when giving additional vitamin D to the child.

Driving and using machines

Calcimonta has no known effect on your ability to drive or use machines.

Calcimonta contains soya oil, sorbitol and sucrose

Calcimonta contains soya oil. If you are allergic to peanut or soya, do not use this medicinal product. Calcimonta contains sorbitol and sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. May be harmful to the teeth.

3. HOW TO TAKE CALCIMONTA CHEWABLE TABLETS

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

Dosage:

The recommended dose is one tablet twice daily. The tablet may be swallowed or chewed.

If you take more Calcimonta Chewable tablets than you should

If you may have taken more Calcimonta Chewable tablets than you should, talk to your doctor or pharmacist immediately.

If you forget to take Calcimonta Chewable tablets

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 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.

Uncommon side effects may affect up to 1 in 100 people: Excessive amounts of calcium in the blood or in the urine may occur with large doses.

Rare side effects may affect up to 1 in 1,000 people: constipation, flatulence, nausea, gastric pain, diarrhoea.

Very rare side effects may affect up to 1 in 10,000 people: itching and rash and dyspepsia. 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.

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 or pharmacist. This includes any side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE CALCIMONTA CHEWABLE TABLETS

Do not store above 25°C. Keep the container tightly closed in order to protect from moisture. Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Do not throw 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.

This leaflet was revised in December 2014.

Additional Information

Calcimonta Chewable tablets 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.

Calcimonta Chewable tablets 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.