

PACKAGE LEAFLET: INFORMATION FOR THE USER

Calcitugg 500 mg chewable tablets
Calcitugg 1000 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.
- 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.

What is in this leaflet:

1. What Calcitugg is and what it is used for
2. What you need to know before you take Calcitugg
3. How to take Calcitugg
4. Possible side effects
5. How to store Calcitugg
6. Contents of the pack and other information

1. What Calcitugg is and what it is used for

Calcitugg are chewable tablets containing calcium which is an important substance in bone formation. Calcitugg is used in the prevention and treatment of calcium deficiency, and as a supplement to specific treatment of osteoporosis. Calcitugg is also used, on prescription from your doctor, as a phosphate binder by patients with a high amount of phosphate in the blood.

2. What you need to know before you take Calcitugg

Do not take Calcitugg

- if you are allergic (hypersensitive) to calcium or any of the other ingredients of Calcitugg.
- if you have excessive amounts of calcium in the blood or in the urine.
- if you have renal stones.

Warnings and precautions

Talk to your doctor or pharmacist before taking Calcitugg

- if you take diuretics (used in the treatment of high blood pressure or oedema) or cardiac glycosides (used to treat heart disorders).
- if you have excessive amounts of calcium in the blood or signs of impaired renal function or have had renal stones in the past.
- if you take high doses of calcium and in addition use products containing vitamin D.
- if you take high doses of calcium and in addition use antacids.

Other medicines and Calcitugg

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

Calcium carbonate may interfere with the absorption of tetracycline preparations 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 Calcitugg.

Medicines containing bisphosphonates should be taken at least one hour before intake of Calcitugg.

Calcium can reduce the effect of levothyroxine. For this reason, levothyroxine should be taken at least four hours before or four hours after Calcitugg.

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 Calcitugg.

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 Calcitugg.

Other medicines that may influence or be influenced by Calcitugg are: thiazide diuretics, and cardiac glycosides.

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

Calcitugg with food and drink

Calcitugg 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 for advice before taking this medicine.

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

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

Driving and using machines

Calcitugg has no known influence on the ability to drive and use machines.

Calcitugg contains isomalt

Calcitugg contains isomalt (E953). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Calcitugg

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

Dosage:

The recommended dose for adults is 500 – 1500 mg calcium per day.

Use in children

The recommended dose for children is 500 – 1000 mg calcium per day.

The tablets can be chewed or sucked.

If you take more Calcitugg than you should

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

If you forget to take Calcitugg

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.

Dyspepsia has occurred with unknown frequency (cannot be estimated from the available data).

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 1000 people)

Constipation, flatulence, nausea, gastric pain, diarrhoea

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

Itching and rash. Milk-alkali syndrome (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.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system listed in Appendix V*](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Calcitugg

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.

Plastic bottle: Do not store above 30°C. Keep the container tightly closed in order to protect from moisture. Shelf life after opening is 6 months.

Blister pack: Do not store above 25°C. Store in the original package in order to protect from moisture.

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 Calcitugg 500 mg contains

The active substance in one tablet is 1250 mg calcium carbonate (equivalent to 500 mg calcium)

What Calcitugg 1000 mg contains

The active substance in one tablet is 2500 mg calcium carbonate (equivalent to 1000 mg calcium)

The other ingredients are:

xylitol (E967), povidone, isomalt (E953), flavouring (orange), magnesium stearate, sucralose (E955), mono- and diglycerides of fatty acids.

What Calcitugg looks like and contents of the pack

Calcitugg are white, round chewable tablets.

Pack sizes:

Plastic bottle: 20, 30, 50, 60, 90, 100, 120 and 180 tablets (500 mg)

30, 60, 90, 100 tablets (1000 mg)

Blister pack: 50 x 1 (unit dose) tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

Manufacturers:

Tablets packed in plastic bottles:

Asker Contract Manufacturing AS
Drammensveien 852, NO-1383 Asker, Norway

Tablets packed in blister:

Tjoapack Netherlands B.V.
Nieuwe Donk 9,
4879 AC Etten-Leur, The Netherlands

This medicinal product is authorised in the Member States of the EEA under the following names:

500 mg:

Belgium: Calci-Chew
Finland: Calcichew appelsiini 500 mg purutabletti
Greece: Calcioral
Luxembourg: Calcichew
Netherlands: Calci-Chew 500 mg
Spain: Mastical
Sweden: Calcitugg 500 mg

1000 mg:

Netherlands: Calci-Chew 1000mg
Sweden: Calcitugg 1000 mg

This leaflet was last revised in 07 June 2023

[To be completed nationally]

Other sources of information

Detailed information on this medicine is available on the web site of {name of MS Agency (link)}.