Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed without a doctor's prescription

CALCIMORE Chewable tablets 600 mg

Active ingredient

Each tablet contains 600 mg calcium carbonate

Inactive ingredients and allergens: see section 2 under 'Important information about some of this medicine's ingredients', and section 6 'Additional information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

Take this medicine according to the instructions in the section about dose in this leaflet. Consult your pharmacist if you need further information. If you are taking Calcimore to treat excess acid and heartburn, consult your doctor if your symptoms of illness get worse or do not improve within 14 days.

1. What is this medicine intended for?

This medicine is used as an antacid. It is also used to treat calcium deficiency.

Therapeutic group: mineral supplement; antacid.

Calcimore - chewable tablets contain calcium, which is important in bone formation. Calcium is found in the diet. Calcium deficiency can happen when your diet or lifestyle does not provide the amount of calcium you need, or when body requirements are increased.

2. Before using this medicine:

- you are sensitive (allergic) to calcium or to any of the other ingredients in this medicine (see section 6)
- you have a disorder that causes excessive amounts of calcium in your blood or urine (hypercalcaemia or hypercalciuria), for example an overactive parathyroid (hyperparathyroidism), overdose of vitamin D
- you have kidney stones
- you eat a low-phosphate diet
- you are taking glycoside medicines for the heart (such as digoxin)
- you have Zollinger-Ellison syndrome (a tumour that secretes gastrin).

Do not use this medicine if:

Special warnings about using this medicine Talk to your doctor before taking Calcimore if:

- you have osteoporosis (brittle bones) and are also unable to move around
- you are on long term treatment, especially if you are taking medicines for a heart disorder (glycosides), or diuretics (used in the treatment of high blood pressure or oedema)
- you have signs of impaired kidney function or a high tendency to kidney stone formation
- if you have **cancer** or other conditions that may have affected your bones

you have diabetes.

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

Children and adolescents

This medicine is not intended for children under 6 years old unless prescribed by a doctor.

Tests and follow-up

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

- you have kidney problems
- you are on **long-term** treatment with Calcimore
- you are already taking additional doses of calcium or vitamin D

Other medicines and Calcimore

If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist. Particularly if you are taking:

- thiazide diuretics; your blood calcium levels must be monitored regularly.
- **glycosides** (heart medicine); you should be monitored by electrocardiogram (ECG) and your blood calcium levels measured.
- **tetracycline antibiotics**; these medicines should be taken at least two hours before, or four to six hours after Calcimore. Calcium carbonate may interfere with the absorption of tetracycline preparations if taken at the same time.
- **levothyroxine** (hormone used to treat thyroid deficiency); this medicine should be taken at least four hours before, or after taking Calcimore.
- 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 Calcimore.
- **bisphosphonates**; should be taken at least one hour before Calcimore.
- 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 Calcimore.

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

Using this medicine and food

This medicine can be taken with or without food.

Pregnancy and breast-feeding

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 Calcimore.

During pregnancy, the daily intake should not exceed 2,500 mg calcium (including food and supplementation). If you are pregnant, you may use Calcimore in case of a calcium deficiency.

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

Driving and using machines

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

Important information about some of this medicine's ingredients

Calcimore contains sucrose (a type of sugar). If you have been told by your doctor that you have an intolerance to some sugars, talk to your doctor before taking this medicine. Calcimore contains less than 1 millimole (23 mg) sodium per dose, so it is considered 'sodium free'.

3. How to use this medicine?

Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

The recommended dosage is usually:

For acid in the stomach: 1-2 tablets as needed.

As calcium supplement: 2 tablets, 1-3 times a day, 1-1½ hours after a meal.

Do not exceed the recommended dose.

Taking this medicine:

Chew the medicine well before swallowing, and drink a full glass of water.

If you have accidentally taken a higher dose, consult your doctor or pharmacist immediately. 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 this medicine

Do not take a double dose to make up for a forgotten tablet.

Do not take medicines in the dark! Check the label and dose <u>every time</u> you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

Like with all medicines, using Calcimore may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Stop taking this medicine and consult a doctor immediately if you experience any of the following side effects.

These side effects may be a sign of Burnett's Syndrome (milk-alkali syndrome) that is very rare (affects less than 1 in 10,000 users):

- frequent urge to urinate
- persistent headache
- loss of appetite, nausea or vomiting
- unusual tiredness or weakness, along with elevated levels of calcium in the blood and kidney impairment.

Uncommon side effects (may affect 1 in 100 users):

• Excessive amounts of calcium in your blood (hypercalcaemia) or in your urine (hypercalcuria) may occur with large doses.

Rare side effects (may affect 1 in 1,000 users):

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

Stopping this medicine can make your heartburn come back.

Very rare side effects (may affect 1 in 10,000 users):

- rash
- hives
- itching

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: https://sideeffects.health.gov.il

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package/label. The expiry date refers to the last day of that month.

Storage conditions

Store below 25°C.

6. Additional information

In addition to the active ingredient, this medicine also contains:

mannitol, sucrose, talc, magnesium stearate, spearmint flavour, peppermint flavour, sodium saccharin.

What the medicine looks like and contents of the pack:

This medicine is available in packs of 10, 20, 50, 60, 100, 1,000 tablets, packaged in trays (blisters).

Not all pack sizes may be marketed.

Manufacturer and registration holder's name and address: Taro Pharmaceutical Industries Ltd., 14 Hakitor St. Haifa Bay, 2624761.

This leaflet was reviewed and approved by the Ministry of Health in September 2021 and revised in November 2021.

Registration number of the medicine in the Ministry of Health's National Drug Registry: 015.95.24731