

Rennie® Orange **Chewable tablets**

Active ingredients:

Every chewable tablet contains:

Calcium carbonate 680 mg (equivalent to 272 mg calcium)

Magnesium carbonate (heavy) 80 mg

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 the medicine according to the instructions in the section about dose in this leaflet. Consult your pharmacist if you need further information. Contact a doctor if your symptoms of illness get worse or do not improve after 14 days.

1. WHAT IS THE MEDICINE INTENDED FOR?

This medicine is intended for the relief of gastric hyperacidity and heartburn.

Therapeutic group: antacid.

Rennie is used for treatment of symptoms resulting from reflux of acidic gastric content to the oesophagus and mouth, causing a sensation of burning or pain behind the sternum. Rennie is also used for treatment of symptoms caused by hyperacidity of gastric content, e.g. in case of heartburn. Rennie can also be used for the treatment of symptoms caused by an ulcer in the upper digestive tract.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- you are sensitive (allergic) to calcium carbonate or to magnesium carbonate or to any of the additional ingredients contained in the medicine (for the list of the inactive ingredients, see section 6 "Additional information").
- you suffer from a severe kidney dysfunction or kidney stones.
- you suffer from high calcium levels or low phosphate levels in the blood.

Special warnings about using this medicine

Before starting treatment with the medicine, tell your doctor if:

- you suffer from sarcoidosis (an inflammatory disease that affects various organs of the body), constipation or haemorrhoids.

Prolonged use of high doses can lead to high calcium or magnesium levels and milk-alkali syndrome, especially if you have kidney problems. Prolonged use increases the risk of developing kidney stones.

Children and adolescents

This medicine is not intended for children under 12 years of age. Under this age, contact a doctor.

Tests and follow up

Before using this medicine, inform the doctor if you are taking a medicine of the thiazide group (such as bendroflumethiazide) to increase urine output, since the doctor may want to monitor your blood calcium levels.

Drug interactions

If you are taking or have recently taken other medicines, including non-prescription medicines and dietary supplements, tell your doctor or pharmacist. Especially if you are taking:

- Antibiotics of the tetracycline or quinolone group.
- Medicines used to treat an irregular heart beat and heart failure of the cardiac glycoside group such as digoxin and digitoxin.
- A medicine of the bisphosphonate group used to treat osteoporosis (bone depletion due to loss of calcium).
- Dolutegravir to treat HIV infection,
- Levothyroxine (a thyroid hormone).
- Eltrombopag (a medicine used to increase the number of platelets in the blood).
- Other medicines that contain fluoride, iron or phosphate
- Medicines of the thiazide group such as bendroflumethiazide (diuretics). Also see above in section "Tests and follow up".

The above medicines may be affected if taken concomitantly with Rennie and you should consult a doctor before taking them with Rennie. To enable optimal action of the medicines that you are taking, it is recommended to take Rennie 1-2 hours after taking these medicines.

Using this medicine and food

Like with all antacids containing calcium, avoid consumption of large quantities of milk or milk products while using this medicine. The maximum recommended quantity of calcium per day in cases of chronic use (longer than 14 days) is 2500 mg. One litre of milk contains 1200 mg calcium and one chewable tablet of Rennie Orange contains 272 mg calcium. If you use several Rennie tablets a day, you should consume less milk (or milk products).

Pregnancy, breast-feeding and fertility

Pregnancy:

The medicine can be used during pregnancy in accordance with the dosage regimen in section 3 "How to use this medicine?". Do not exceed the recommended dosage or the dosage instructed by your doctor or pharmacist and do not use this medicine for more than 14 days. Do not consume excess milk and milk products, since the medicine contains a significant amount of calcium. The purpose of this warning is to prevent excess consumption of calcium which may cause milk-alkali syndrome. Before using any medicine, consult a doctor or pharmacist.

Breast-feeding:

This medicine can be used during breastfeeding in accordance with the recommended dosage specified below in section 3 "How to use this medicine?".

Fertility:

There is no evidence that Rennie affects fertility at the recommended dose.

Driving and using machines

The medicine is not expected to affect the ability to drive or operate machines.

Important information about some of this medicine's ingredients

Each tablet contains 475 mg sucrose. If you have been told by a doctor that you are suffering from a sensitivity to certain sugars, consult the doctor before taking Rennie® Orange.

3. HOW TO USE THIS MEDICINE?

Check with the doctor or pharmacist if you are uncertain about the dose and treatment regimen of the medicine.

The recommended dosage is usually:

- **Adults and children over 12 years of age:** 1-2 tablets to be sucked or chewed, as needed, preferably about one hour after food and before bedtime.
- For treatment of heartburn, 1-2 additional tablets can be taken between these times.

- Do not take more than 10 tablets in 24 hours.
- **This medicine is not intended for children under 12 years of age.**
- It is recommended to wait about one to two hours between taking other medicines and taking Rennie.
- **Children under the age of 12:** The safety and efficacy of this medicine have not been proven in this population.

Do not exceed the recommended dose.

Treatment duration

Do not use this medicine for more than two weeks unless a doctor has advised you to do so. If the symptoms continue for longer than 14 days from taking the medicine, contact a doctor to rule out more severe medical conditions that may be masked by the use of Rennie (or any other antacid).

Intake mode

Chew or suck 1-2 Rennie tablets as described above in section 3 "How to use this medicine?". Rennie tablets can be taken without water.

If you have accidentally taken a higher dose, contact a doctor or pharmacist immediately.

Long-term use of high dosages of calcium carbonate may lead to stomach and digestive system problems such as nausea, vomiting and unusual muscle weakness. In such cases, stop using the medicine, contact a doctor immediately and drink plenty of fluid. Also see section 4 "**Side effects**" under "**Discontinue use and contact a doctor immediately upon occurrence of**".

If you have taken an overdose, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

If you forget to take this medicine at the scheduled time, never take a double dose to compensate for the forgotten dose.

Do not take medicines in the dark! Check the label and dose every time you take a 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

As with any medicine, using Rennie may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Discontinue use and contact a doctor immediately upon occurrence of:

- Very **rare** allergic effects which have been reported, such as rash, rash with intense itching and formation of bumps (hives), itching, breathing difficulties and swelling of the face, mouth or throat and anaphylactic shock (a severe, life-threatening allergic reaction; possible symptoms are: low blood pressure, heart palpitations, breathing difficulties, bronchospasm, skin reactions, abdominal pains or cramps, vomiting and diarrhoea).

Prolonged use of high dosages of the medicine may result in excessively low level of stomach acid (high stomach pH), excessively high blood levels of calcium and magnesium, especially in patients with kidney dysfunction. Excessive calcium in the blood may be manifested by the following symptoms: fatigue, confusion, increased urine production, increased thirst and dehydration. You may suffer from nausea, vomiting, upset stomach, constipation, diarrhoea and muscle weakness.

Long-term use of Rennie in combination with milk or milk products may lead to milk alkali syndrome, which may result in high blood calcium levels. The following symptoms of this syndrome may occur: decreased sense of taste, headaches, kidney disorders, fatigue and emergence of lumps under the skin.

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 any other medicine 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) that appears on the package and blister. The expiry date refers to the last day of that month.
- **Storage conditions:** store at a temperature below 25°C. Store in the original package.
- Do not throw away medicines via wastewater or household waste. Ask the pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

6. ADDITIONAL INFORMATION

In addition to the active ingredients, the medicine also contains:

Sucrose, orange flavour, talc, maize starch pregelatinised, potato starch, magnesium stearate, light liquid paraffin, saccharin sodium.

What the medicine looks like and contents of the pack

Chewable, square, concave, cream-white tablets, with "RENNIE" imprinted on both sides. The tablets have an orange scent.

A pack of 36 tablets.

Registration holder's/Importer's name and address:

Bayer Israel Ltd., 36 Hacharash St., Hod Hasharon 45240.

Revised in June 2022 according to MoH guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 144 16 32043 00