

Rennie® Orange

Chewable tablets

Active ingredients:

Calcium carbonate 680 mg

Magnesium carbonate (heavy) 80 mg

Inactive ingredients and allergens in the medicine: 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 provided in the dosing section of this leaflet. Consult a pharmacist if you need further information. Contact a doctor if the disease symptoms worsen 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. Each tablet neutralizes 16 mEq acid.

Therapeutic group: antacid

Rennie® is used for treatment of symptoms resulting from reflux of acidic gastric content to the esophagus 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 you suffer from heartburn.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- you are sensitive to calcium carbonate or to magnesium carbonate or to any of the additional ingredients contained in the medicine (for the list of all the 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 severe kidney dysfunction, sarcoidosis (an inflammatory disease that affects various organs of the body) or if you suffer from chronic problems/ illnesses of the stomach or digestive system.

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) for increasing your 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 nutritional supplements, tell the doctor or pharmacist. Especially if you are taking:

- Medicines that contain iron or phosphate.
- Antibiotics of the tetracycline or quinolone group.
- Medicines used to treat arrhythmias and heart failure of the cardiac glycoside group such as digoxin and digitoxin.
- Medicines of the thiazide group such as bendroflumethiazide (diuretics). Also see above in section "Tests and follow up".
- Fluorides.
- Levothyroxine (a thyroid hormone).
- Eltrombopag (a medicine used to increase the number of platelets in the blood).

The above medicines may be affected if taken concomitantly 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.

Pregnancy and breastfeeding

The medicine can be used during pregnancy but taking high doses for prolonged periods should be avoided. Do not exceed the recommended dosage. Avoid overconsumption of milk and milk products (one liter contains maximum 1.2 gram calcium), since the medicine contains a significant amount of calcium. Before using any medicine, consult a doctor or pharmacist.

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

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 time points.
- Do not take more than 10 tablets per day.
- **This medicine is not intended for children under 12 years of age.**
- Avoid prolonged use.
- It is recommended to wait about one to two hours between taking other medicines and taking Rennie®.

Do not exceed the recommended dose.

Treatment duration

Do not use this medicine for more than two weeks unless your doctor has advised you to do so. If the symptoms continue for longer than 14 days from starting treatment with 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 the medicine may lead to gastric and digestive system problems such as nausea, vomiting and unusual muscle weakness. In such cases, stop using the medicine, contact a doctor immediately and ensure adequate fluid intake. Also see section 4 "**Side effects**" sub-section "**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 go to a hospital emergency room and bring the medicine package with you.

If you forget to take the 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.

Side effects are unlikely at the recommended dosages.

Discontinue use and contact a doctor immediately upon occurrence of:

- **Rare** allergic effects which have been reported, such as rash, 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, shock, heart palpitations, breathing difficulties, bronchospasm, skin reactions, abdominal pains or cramps, vomiting and diarrhea).

Long-term use at high dosages of the medicine may result in excessively high blood levels of calcium and magnesium, especially in patients suffering from kidney dysfunction. This may be manifested by the following symptoms: nausea, vomiting, stomach problems, diarrhea, fatigue, muscle weakness, confusion, increased urine production, increased thirst and dehydration.

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. 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, paraffin light liquid, 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 name and address:

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

Manufacturer's name and address:

Delpharm Gaillard, Gaillard, France, 33 rue de l'Industrie 74240 Gaillard, France.

Revised in September 2020.

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