

PATIENT PACKAGE INSERT IN ACCORDANCE WITH
THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986
This medicine is dispensed without a doctor's prescription

Rennie® Ice Chewable tablets



Active ingredients:

Calcium carbonate 680 mg (272 mg available calcium)
Magnesium carbonate (heavy) 80 mg

Inactive ingredients: see chapter 6 "Further Information".

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine is not intended for children under 12 years of age. Under this age, refer to a doctor. Use this medicine properly. Consult a pharmacist if you need further information. Refer to a doctor if the 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 approximately 16 mEq acid.

Therapeutic group: antacid

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 chapter 6).
- you are suffering from a severe kidney disease.
- you are suffering from high calcium levels in the urine or from kidney stones.
- you are suffering from high calcium levels or from low phosphate levels in the blood.

Special warnings regarding use of the medicine

- 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 of taking the medicine, refer to a doctor to rule out more severe medical conditions.
- This medicine is not intended for children under 12 years of age.

Before starting treatment with the medicine, inform the doctor if:

- you are suffering, or have suffered in the past, from impaired function of the kidney/urinary system. The doctor may refer you for blood tests.
- you are suffering from sarcoidosis (an inflammatory disease that affects various organs of the body) or if you suffer from chronic problems/illnesses of the digestive system.
- you are sensitive to any food or medicine.

If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, inform the doctor or pharmacist. Especially if you are taking:

- Preparations that contain iron or phosphate.
- Antibiotics from the tetracycline or quinolone group.
- Digoxin and digitoxin (used to treat heart disorders and heart failure).
- Medicines from the thiazide group (diuretics).
- Fluorides.
- Levothyroxine (a thyroid hormone).
- Eltrombopag (a medicine used to increase the number of platelets in the blood). It is recommended to wait at least 4 hours before or after taking eltrombopag and taking Rennie.

Use of the medicine and food

Avoid consumption of large quantities of milk or milk products while using this medicine.

Pregnancy and breastfeeding

Can be used by pregnant or breastfeeding women. Do not exceed the recommended dosage. Avoid prolonged use and overconsumption of milk and milk products, since the medicine contains a significant amount of calcium. Before using, consult a doctor or pharmacist.

Driving and use of machinery

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

Important information regarding some of the ingredients of the medicine

This medicine contains 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.

3. HOW SHOULD YOU USE THE MEDICINE?

Check with the doctor or pharmacist if you are uncertain.

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 preparation 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 Rennie.
- **Do not exceed the recommended dose.**

Tests and follow up

- Upon long-term treatment with this medicine, it is recommended to test blood calcium, magnesium and phosphate levels, especially in patients suffering from kidney failure.
- Before using this medicine, inform the doctor if you are already taking a medicine from the thiazide group, as the doctor may want to monitor your blood calcium levels.

Long-term use of high dosages of the medicine may lead to digestive system problems such as: nausea, vomiting, constipation, and to tiredness and unusual muscle weakness. In such cases, stop using the medicine, refer to a doctor immediately and ensure adequate water intake. Also see chapter 4 "Side Effects" section "**Discontinue use and refer to a doctor immediately upon occurrence of**".

If you took an overdose, or if a child has accidentally swallowed the medicine, immediately proceed to a hospital emergency room and bring the package of medicine with you.

If you forgot to take this medicine at the required time, never take a double dose.

Do not take medicines in the dark! Check the label and the dose **each time** you take medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, ask the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of the medicine may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Side effects are unlikely at the recommended dosages.

Discontinue use and refer to 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 can result in raised blood calcium/magnesium levels, especially in patients suffering from kidney dysfunction. This can 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 at high dosages or in combination with large quantities of milk or milk products may lead to "milk alkali" syndrome, manifested by high blood calcium levels; the following symptoms may occur: loss of sense of taste, headache, kidney disorders, fatigue, and emergence of lumps under the skin.
- Also see chapter "**How Should You Use The Medicine?**".

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Side effects can be reported to the Ministry of Health by clicking on the link "Reporting side effects following drug treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: <https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>

5. HOW SHOULD THE MEDICINE BE STORED?

- **Avoid poisoning!** This medicine and any other medicine must be kept in a safe place out of the reach of children and/or infants in order to avoid poisoning. **Do not induce vomiting** unless explicitly instructed to do so by the 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 in a temperature below 25°C.
- Store in the original packaging.

6. FURTHER INFORMATION

In addition to the active ingredients, the medicine also contains: Sucrose, Talc, Xylitab 100, Pregelatinised maize starch, Cooling flavour, Mint flavour, Potato starch, Magnesium stearate, Light liquid paraffin. Each tablet contains 475 mg sucrose.

What the medicine looks like and the contents of the package:

Chewable, square, concave, cream-white tablets, with occasional slight speckles, with "RENNIE" imprinted on both sides. The tablets have a refreshing mint scent.

Approved pack size: 48 tablets.

Registration holder and address:

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

Manufacturer and address:

Delpharm Gaillard, Gaillard, France.

The format of this leaflet was determined by the Ministry of Health and its content was checked and approved in February 2016.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 147 91 33516 00

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