

Package leaflet: Information for the user
Rennie® SUGAR FREE
680mg/80mg CHEWABLE TABLETS

Calcium carbonate and Magnesium carbonate

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 has 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.
- You must contact a doctor if you do not feel better or if you feel worse after 14 days.

WHAT IS IN THIS LEAFLET

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1. WHAT RENNIE® SUGAR FREE IS AND WHAT IT IS USED FOR?

Rennie® Sugar Free Chewable Tablets get to work within minutes to provide fast, effective relief from heartburn, indigestion and acid reflux. Each tablet contains two antacids – calcium carbonate and magnesium carbonate – that work quickly and effectively to neutralise excess acid in the stomach. Through this neutralisation they protect the stomach and the food pipe against damaging effects of the excess acid. You must contact a doctor if you do not feel better or if you feel worse after 14 days.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE RENNIE® SUGAR FREE

Do not take Rennie® Sugar Free:

- If you have severe kidney disease or suffer from kidney stones.
- If you have high calcium levels in the blood, kidneys or urine.
- If you have low phosphate levels in the blood.
- If you are allergic (hypersensitive) to any of the ingredients (*listed in Section 6*).

Warnings and precautions:

As with other antacid products, taking these tablets can mask the symptoms of other, more serious, underlying medical conditions. Long term use of high doses can cause high calcium and magnesium levels in the blood. Long term use may increase the risk of developing kidney stones. Do not exceed the stated dose. If symptoms persist after fourteen days consult your doctor.

Patients aged 55 years or older with unexplained and persistent heartburn should contact their doctor before taking Rennie® Sugar Free.

Rennie® is designed to help relieve pain and discomfort associated with excess stomach acid.

Pain/discomfort associated with cardiac conditions may on occasion mimic indigestion; such pain will not respond to Rennie®, therefore it is recommended that medical advice be sought if the pain does not go away.

Consult your doctor before taking Rennie® Sugar Free if you have any kidney problems.

Other medicines and Rennie® Sugar Free

- Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.
- If you are taking antibiotics (tetracyclines, quinolones), medication for heart failure (e.g. digoxin), thiazide diuretics (water tablets), bisphosphonates (used for the treatment of osteoporosis), dolutegravir

(an anti-retroviral medicine used for the treatment of HIV infection), levothyroxine (a thyroid medication) or other prescribed medicines (e.g. fluorides, phosphates, iron containing products, eltrombopag) speak to your doctor or pharmacist before taking Rennie® Sugar Free because it can affect how these medicines work.

- To maximise the benefit of all medicines being used, take Rennie® Sugar Free 1 to 2 hours after taking any other medicines.

Rennie Spearmint with food and drink:

Rennie Spearmint should not be taken with large amounts of milk or dairy products.

Pregnancy and breast feeding:

If you are pregnant or breast-feeding, think you might be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Rennie® Sugar Free can be used during pregnancy if taken as instructed and if prolonged use of high doses is avoided. Rennie® Sugar Free can be used while breast-feeding if taken as instructed.

As Rennie® Sugar Free provides a substantial amount of calcium in addition to dietary calcium intake pregnant women should strictly limit their use of Rennie® Sugar Free tablets to the maximum recommended daily dose and avoid concomitant excessive intake of milk (1 litre contains up to 1.2g elemental calcium) and dairy products.

Rennie Sugar Free contains sorbitol and sodium

This medicine contains 400 mg sorbitol in each tablet. Sorbitol is a source of fructose. If your doctor has told you that you have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you take or receive this medicine.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say it is essentially 'sodium-free'.

3. HOW TO TAKE RENNIE® SUGAR FREE

Adults: 1 or 2 tablets to be sucked or chewed as required, up to a maximum of 11 tablets a day.

Children and adolescents below age 18: Not recommended.

If you take more Rennie® Sugar Free than you should:

Drink plenty of water and consult your doctor or pharmacist. Symptoms of an overdose include nausea and vomiting, constipation, tiredness, increased urine production, increased thirst, dehydration and abnormal muscular weakness.

If you have any questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them. Side effects are unlikely at the recommended dose.

Very rarely severe allergic reactions e.g. rashes, itching, swelling or shortness of breath may occur. If you experience these reactions stop treatment and contact a doctor or emergency department immediately.

Long term use of high doses can cause high calcium and magnesium levels in the blood, nausea, vomiting, stomach discomfort, diarrhoea and milk-alkali syndrome, especially in people with kidney conditions. This can cause nausea and vomiting, constipation, headache, alterations in taste sensations and muscular weakness.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance; Website: www.hpra.ie.

By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE RENNIE® SUGAR FREE

Keep this medicine out of the sight and reach of children. Do not store above 25°C and keep in the original pack.

Do not use this medicine after the expiry date which is stated on the carton and blister. The expiry date refers to the last day of that month.

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 FURTHER INFORMATION

What Rennie® Sugar Free contains:

The active substances are: calcium carbonate 680mg and heavy magnesium carbonate 80mg.

The other ingredients are sorbitol (E420), magnesium stearate, potato starch, pregelatinised maize starch, talc, spearmint flavour, liquid paraffin, saccharin sodium.

What Rennie® Sugar Free looks like and contents of the pack:

Rennie® Sugar Free are white square tablets engraved “RENNIE” on both faces.

Rennie® Sugar Free are available in packs of 24, 48, and 96 chewable tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

Marketing Authorisation Holder:

Bayer Limited, The Atrium, Blackthorn Road, Dublin 18.

Manufacturer:

Delpharm Gaillard, 74240 Gaillard, France.

Label last revised: to be inserted upon approval.