

Package leaflet: Information for the user

Rennie[®] Deflatine

680mg/ 80mg/ 25mg CHEWABLE TABLETS

Calcium carbonate, magnesium Carbonate and simeticone

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 7 days.

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1. WHAT RENNIE[®] DEFLATINE IS AND WHAT IT IS USED FOR

Rennie[®] Deflatine relieves the pain and discomfort of bloating, flatulence, and trapped wind. Each tablet is formulated with simeticone, a highly effective anti-foaming agent that causes the trapped air bubbles to combine and disperse, helping to eliminate the symptoms discreetly and without embarrassment. Rennie Deflatine also contains antacids which provide effective relief from heartburn, indigestion and acid reflux. You must contact a doctor if you do not feel better or if you feel worse after 7 days.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE RENNIE[®] DEFLATINE

Do not take Rennie[®] Deflatine:

- 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.

Do not exceed the stated dose. If symptoms persist after seven days consult your doctor.

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

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® Deflatine if you have any kidney problems. Long term use may increase the risk of developing kidney stones.

Other medicines and Rennie® Deflatine

- 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® Deflatine because it can affect how these medicines work.
- To maximise the benefit of all medicines being used, take Rennie® Deflatine 1 to 2 hours after taking any other medicines.

Rennie® Deflatine with food and drink

Avoid taking Rennie® Deflatine with large amounts of milk or dairy products.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding, think you might be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Rennie® Deflatine can be used during pregnancy and breastfeeding, if taken as instructed and if prolonged use of high doses is avoided.

As Rennie® Deflatine provides a substantial amount of calcium in addition to dietary calcium intake pregnant women should strictly limit their use of Rennie® Deflatine 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® Deflatine contains sorbitol

This product contains 430 mg sorbitol (E420). 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.

3. HOW TO TAKE RENNIE® DEFLATINE

Adults: 1 or 2 tablets to be sucked or chewed as required, up to a maximum of 11 tablets a day. Do not take for longer than 2 weeks.

Children and adolescents below age 18: Not recommended.

If you take more Rennie® Deflatine 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, swelling, itching 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® DEFLATINE

Keep this medicine out of the sight and reach of children. Do not store above 25°C. 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 waste water 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 OTHER INFORMATION

What Rennie® Deflatine contains:

The active substances are: calcium carbonate 680mg, heavy magnesium carbonate 80mg and simeticone 25mg.

The other ingredients are sorbitol (E420), magnesium stearate, potato starch, pregelatinised maize starch, talc, mint flavour, lemon flavour.

What Rennie® Deflatine looks like and contents of the pack:

Rennie® Deflatine are white, circular, flat tablets, with a single score line on one surface.

Rennie® Deflatine are available in packs of 18 chewable tablets.

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