

Package leaflet: Information for the user

Rennie 750 mg medicated chewing-gum

Calcium 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 talk to a doctor if you do not feel better or if you feel worse after 7 continuous days of treatment.

What is in this leaflet

1. What Rennie Gum is and what is it used for
2. What you need to know before you take Rennie Gum
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1. What Rennie Gum is and what is it used for

Rennie Gum is a sugar-free, mint-flavoured medicated chewing-gum. It provides a fast and effective relief from:

- heartburn,
- stomach pain
- other symptoms associated with too much stomach acid leading to acid reflux and indigestion.

You must talk to a doctor if you do not feel better or if you feel worse after 7 continuous days of treatment.

2. What you need to know before you take Rennie Gum

Do not take Rennie Gum if you are/have

- allergic to calcium carbonate or any of the other ingredients of this medicine (listed in section 6)
- high calcium levels in the blood
- high calcium levels in urine, or kidney stones, which consist of calcium
- severely reduced kidney function
- low phosphate levels in the blood

Warnings and precautions

Do not exceed the stated dose or use Rennie Gum for more than 7 days unless recommended by a doctor.

Talk to your doctor or pharmacist before taking Rennie Gum if you have mild or moderate kidney problems as regular blood tests are recommended.

Children under 12 years

Rennie Gum is not recommended in this age group.

Other medicines and Rennie Gum

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

If you are taking any of the following medicines speak to your doctor or pharmacist before taking Rennie Gum because it can affect how these medicines work:

- medicines to treat bacterial infections (antibiotics) called tetracyclines or quinolones
- medicines to treat osteoporosis and similar conditions called bisphosphonates
- medicines to treat fluid retention and high blood pressure called thiazide diuretics
- digoxin (to treat some heart conditions)
- dolutegravir (to treat HIV infection)
- levothyroxine (to treat thyroid hormone deficiency)
- eltrombopag (to increase the number of platelets)
- fluorides (to prevent dental cavities)
- phosphates (e.g. to clear the bowel before a surgical procedure)
- iron-containing medicines
- vitamin D-containing medicines

Take Rennie Gum 1 to 2 hours after taking any other medicines to maximise the benefit of all medicines being used.

Rennie Gum with food and drink

Avoid large amounts of milk or dairy products when taking Rennie Gum.

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 Gum can be used during pregnancy if taken as instructed and if prolonged use of high doses is avoided.

Rennie Gum can be used while breast-feeding if taken as instructed.

Rennie Gum provides a substantial amount of calcium in addition to dietary calcium. Therefore, while taking Rennie Gum pregnant women should:

- strictly limit their use of Rennie Gum to the maximum recommended daily dose
- avoid excessive intake of milk (1 litre contains up to 1.2 g calcium) and dairy products

Driving and using machines

Rennie Gum has no influence on the ability to drive and use machines.

Rennie Gum contains isomalt, sorbitol and sodium

This medicine contains isomalt and 170 mg sorbitol in each medicated chewing-gum. Sorbitol is a source of fructose. If your doctor has told you that you (or your adolescent) 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 (or your adolescent) take or receive this medicine.

This medicine contains less than 1 mmol sodium (23 mg) per medicated chewing-gum, that is to say essentially sodium-free.

3. How to take Rennie Gum

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults and children from 12 years

The recommended dose is 1 or 2 gums as a single dose after a meal and at bedtime, in case heartburn or stomach pain occurs.

Additional doses may be taken if the symptoms reoccur, but do not exceed a maximum of 8 gums per day.

For pregnant women, do not exceed a maximum of 5 pieces per day.

Chew the gums for a minimum of 15 minutes. Do not swallow the remaining gum; however, dispose of it sensibly.

As with all medicines to reduce stomach acid, inform your doctor if symptoms persist in spite of treatment. Diagnostic measures are strongly recommended in order to rule out a more serious disease.

If you take more Rennie Gum than you should

Drink plenty of water and consult your doctor or pharmacist. Symptoms of an overdose include nausea and vomiting, tiredness, constipation and muscle weakness.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop treatment immediately and seek medical advice if you experience any of the following:

- allergic reactions to ingredients, which have been rarely reported like
 - rash, itching
 - difficulty in breathing
 - swelling of the face, mouth or throat
 - sudden severe allergic shockTypical symptoms are low blood pressure, shock, pounding of the heart, breathing difficulties, narrowing of lung airways, skin reactions, abdominal pain or cramps, vomiting, diarrhoea and constipation.
- high blood levels of calcium may occur due to long term use of high doses, especially in people with kidney conditions.
- muscle weakness
- nausea, vomiting, stomach discomfort, diarrhoea, constipation
- milk-alkali syndrome may occur in exceptional cases, due to long term use of high doses
This can cause reduced sense of taste, an increase of calcium in the blood and soft tissues, an increase of urea in the blood, fatigue and headache.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. 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 Gum

Keep this medicine out of the sight and reach of children.

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.

Store below 30°C.

Store in the original package in order to protect from moisture.

Do not throw away any unused medicines via 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 Gum contains

The active substance is calcium carbonate. Each piece of medicated chewing-gum contains 750 mg of calcium carbonate.

The other ingredients are acesulfame potassium, isomalt, menthol, copovidone, sorbitol, sucralose, magnesium stearate, brilliant blue colourant, peppermint extra flavour and chewing-gum base.

What Rennie Gum looks like and contents of the pack

The bi-layer, 16 mm round, medicated chewing-gums are packed into PVC/PVdC/aluminium blisters. These are contained in cardboard boxes with 10 or 20 medicated chewing-gums.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Bayer Limited, 1st Floor, The Grange Offices, The Grange, Brewery Road, Stillorgan, Co. Dublin, A94 H2K7, Ireland

Manufacturer

Fertin Pharma A/S
Dandyvej 19
7100 Vejle
Denmark

This medicinal product is authorised in the Member States of the EEA under the following names:

France: RENNAXT, gomme à mâcher

Hungary: Rennie Gum cukormentes 750 mg gyógyszeres rágógumi

Ireland: Rennie 750 mg Medicated Chewing-Gum

Italy: Citadvance 750 mg gomma damasticare medicataGusto menta fredda

Netherlands: Rennie kauwgom calciumcarbonaat 750 mg suikervrij

Slovenia: Rupugum 750 mg zdravilni žvečilni gumiji

This leaflet was last revised in XXXX.