

Package leaflet: Information for the user

Rennie® Orange

500mg CHEWABLE TABLETS

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 contact a doctor if you do not feel better or if you feel worse after 7 days.

WHAT IS IN THIS LEAFLET

1. What Rennie® Orange is and what it is used for
2. What you need to know before you take Rennie® Orange
3. How to take Rennie® Orange
4. Possible side effects
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1. WHAT RENNIE® ORANGE IS AND WHAT IS IT USED FOR?

Rennie® Orange Chewable tablets get to work to provide fast-effective relief from heartburn, indigestion and acid reflux.

Each antacid tablet works to neutralise excess acid in the stomach.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE RENNIE® ORANGE

Do not take Rennie® Orange:

- 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 calcium carbonate or any of the ingredients of this medicine (*listed in Section 6*).

Warnings and precautions:

Consult your doctor before taking Rennie® Orange if you have any kidney problems. This product contains sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. 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® Orange.

Rennie® is designed to help relieve pain 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.

Other medicines and Rennie® Orange:

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

Rennie Orange with food and drink:

Rennie Orange should not be taken 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® Orange can be used during pregnancy if taken as instructed and if prolonged use of high doses is avoided. Rennie® Orange can be used while breastfeeding if taken as instructed.

As Rennie® Orange provides a substantial amount of calcium in addition to dietary calcium intake pregnant women should strictly limit their use of Rennie® Orange 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 Orange contains sucrose and ponceau 4R

This product contains sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. This product also contains ponceau 4R (E124) which may cause allergic reactions.

3. HOW TO TAKE RENNIE® ORANGE

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

Children under 12: Not recommended.

If you take more Rennie® Orange 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 blood levels of calcium, nausea, vomiting, stomach discomfort, diarrhoea and milk-alkali syndrome, especially in people with kidney conditions. This can cause nausea, vomiting, constipation, alterations in taste sensation & 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; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE RENNIE® ORANGE

Keep this medicine out of the sight and reach of children. Do not store above 25°C. Store in the original package in order to protect from moisture.

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 OTHER INFORMATION

What Rennie® Orange contains:

The active substance is: calcium carbonate 500mg.

The other ingredients are sucrose, potato starch, pregelatinised maize starch, magnesium stearate, talc, citric acid, saccharin, orange flavour, ponceau 4R (E124) and quinoline yellow (E104)

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

Rennie® Orange are orange coloured, square tablets with rounded corners.

Rennie® Orange are available in packs of 8, 12, 24, 32, 48, 60, 64, 72, 80, 96 or 120 tablets.

They are also available in bottles containing 30, 70, 100 or 150 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