

Rennie®

ORANGE

500mg CHEWABLE TABLETS

Calcium carbonate



Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription. However, you still need to take Rennie® Orange tablets carefully to get the best results from them. Keep this leaflet, you may need to read it again. Ask your pharmacist if you need more information or advice. You must contact a doctor if your symptoms worsen or do not improve. If you have any unusual effects after taking Rennie® Orange, tell your doctor or pharmacist.

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1. WHAT IS RENNIE® ORANGE AND WHAT IS IT USED FOR?

Rennie® Orange is an antacid tablet which relieves stomach upset due to excess acid and heartburn (e.g. indigestion, hyperacidity, flatulence, dyspepsia, biliousness and acid indigestion).

2. 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 any of the ingredients (*listed in Section 6. Further information*).

Take special care with Rennie® Orange:

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.

Taking other medicines:

- 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), 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.

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.

Pregnancy and breast feeding: Ask your doctor or pharmacist for advice before taking any 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 breast-feeding 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.

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, Rennie® Orange 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 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, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. 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 out of reach and sight of children. Do not store above 25°C. Store in the original package in order to protect from moisture.

Do not use Rennie® Orange after the expiry date which is stated on the carton and blister. The expiry date refers to the last day of that month. Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Rennie® Orange contains:

Each tablet contains the active ingredient: 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) If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

What Rennie® Orange looks like and the 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: February 2015