

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 vou.

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

1. What Rennie Orange Flavour is and what it is used for

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- **Rennie Orange Flavour**
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WHAT IT IS USED FOR

Rennie Orange Flavour fast-acting tablets get to work within minutes to provide effective relief from heartburn, indigestion and acid reflux.

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

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

- Do not take Rennie Orange Flavour if you: Have severe kidney disease.
- Have high calcium in the urine or kidney stones. Have high calcium or low phosphate levels in
- the blood. • Are allergic (hypersensitive) to any of the
- ingredients (listed in Section 6).

Warnings and precautions:

Do not exceed the stated dose. Rennie Orange Flavour should not be used for more than 14 days without consulting a doctor. Please consult your doctor or pharmacist if you have mild or moderate kidney problems as regular blood tests should be carried out.

Other medicines and Rennie Orange Flavour:

- 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 any of the following medicines speak to your doctor or pharmacist before taking Rennie Orange Flavour because it can affect how these medicines work.
- Tetracyclines and guinolones (antibiotics) - Bisphosphonates (used for the treatment

- of osteoporosis) - Dolutegravir (an anti-retroviral medicine
- used for the treatment of HIV infection) - Levothyroxine (a thyroid hormone)
- - Eltrombopag (used to increase the number of platelets)
- Digoxin (used for some heart conditions) - Thiazide diuretics (water tablets to treat fluid retention and high blood pressure)
- Fluorides (for preventing dental caries) - Phosphates (for clearing the bowel
- before a surgical procedure)
- Iron supplements
- To maximise the benefit of all medicines being used, take Rennie Orange Flavour at least 4 hours before or after taking eltrombopag and 1 to 2 hours after taking any other medicines.

Rennie Orange Flavour with food and drink Avoid taking Rennie Orange Flavour with large amounts of milk or dairy products.

Pregnancy and breastfeeding:

Rennie Orange Flavour can be used during pregnancy and breastfeeding if taken as instructed. As Rennie Orange Flavour provides a substantial amount of calcium in addition to dietary calcium intake, pregnant women should strictly limit their use of Rennie Orange Flavour to the maximum recommended daily dose and avoid concomitant, excessive intake of milk (1 litre contains up to 1.2 g elemental calcium) and dairy products. 7001606 / 0723GB

Rennie Orange Flavour 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. May be harmful to the teeth. This product also contains ponceau 4R (E124) which may cause allergic reactions.

3. HOW TO TAKE RENNIE® ORANGE FLAVOUR

Adults and children over 12 years only: 2 tablets to be sucked or chewed, as required, preferably 1 hour after meals and before bedtime. For heartburn an extra 2 tablets may be taken between these times. Do not take more than 16 tablets a day.

Children under 12 years: Not recommended.

If symptoms persist after 14 days consult your pharmacist or doctor. Prolonged use should be avoided.

If you take more Rennie Orange Flavour than you should:

Drink plenty of water and consult your doctor or pharmacist. Symptoms of an overdose include nausea and vomiting, tiredness, constipation and 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. If you experience the following side effects stop treatment immediately and seek medical advice. Rarely allergic reactions to ingredients have been reported, e.g. rashes, itching, difficulty in breathing and swelling of the face, mouth or throat and anaphylactic shock (anaphylactic shock is a severe sudden allergic reaction, symptoms of which are low blood pressure, shock, palpitations, difficulty in breathing, bronchospasm, skin reactions, abdominal pain or cramps, vomiting and diarrhoea). Long term use of high doses can cause high blood levels of calcium especially in people with kidney conditions. Symptoms of this may include nausea, vomiting, upset stomach, constipation, diarrhoea, tiredness, muscular weakness, headache, kidney problems and impaired sense of taste. In exceptional cases, long term use of high doses can lead to milk alkali syndrome, which can cause high blood levels of calcium.

6. Contents of the pack and other information 1. WHAT RENNIE® ORANGE FLAVOUR IS AND

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 the Yellow Card Scheme at: <u>www.mhra.gov.uk/yellowcard</u> or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

5. HOW TO STORE RENNIE® ORANGE FLAVOUR

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 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 Orange Flavour contains: The active substance is: calcium carbonate 500mg. The other ingredients are sucrose, potato starch, pregelatinised maize starch, talc, magnesium stearate, citric acid, saccharin, orange flavour, Ponceau 4R (E124) aluminium lake, and Quinoline yellow (E104) aluminium lake.

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

Rennie Orange Flavour are orange-coloured square tablets with rounded edges and are occasionally spotted.

Rennie Orange Flavour are available in packs of 8. 12, 24, 32, 48, 64, 72, 96, 120 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

Marketing Authorisation Holder: Baver plc, 400 South Oak Way, Reading, RG2 6AD, UK. consumerhealthuk@bayer.com

Manufacturer: Delpharm Gaillard, 74240 Gaillard, France.

This leaflet was last revised in: July 2023.

Bayer