

PACKAGE LEAFLET: INFORMATION FOR THE USER

RENNIE DUAL ACTION TABLETS

Calcium carbonate, Magnesium carbonate, Alginic acid
Chewable tablets

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 14 days.

What is in this leaflet

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1. WHAT RENNIE DUAL ACTION TABLETS ARE AND WHAT THEY ARE USED FOR

Rennie Dual Action tablets provide relief from heartburn and acid indigestion.

Rennie Dual Action tablets work in two different ways:

1. Alginic acid forms a protective barrier in the stomach to stop acid escaping upwards, soothing that burning pain in your chest
2. Calcium carbonate and magnesium carbonate provide rapid and long lasting neutralization of excess acid in the stomach

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE RENNIE DUAL ACTION TABLETS

Do not take Rennie Dual Action Tablets:

- If you have severe kidney disease or suffer from kidney stones.
- If you have high calcium or low phosphate levels in the blood.
- If you are allergic to any of the ingredients.

Warnings and precautions:

As with other antacid products, taking these tablets can mask the symptoms of other, more serious, underlying medical conditions. If symptoms persist after fourteen days consult your doctor.

Patients aged 55 years or older with unexplained and persistent heartburn should contact their doctor before taking Rennie Dual Action Tablets.

Please consult your doctor or pharmacist before taking Rennie Dual Action Tablets if you have any kidney problems, have been diagnosed with sarcoidosis (inflammation disease that affects multiple organs in the body), or suffer from severe or chronic gastro-intestinal symptoms or diseases.

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.

Other medicines and Rennie Dual Action Tablets:

- Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.
- If taking antibiotics (tetracyclines, quinolones), cardiac glycosides (digoxin, digitoxin), levothyroxine (a thyroid hormone), bisphosphonates (used for the treatment of osteoporosis), dolutegravir (an anti-retroviral medicine used for the treatment of HIV infection), eltrombopag (a medicine used to increase the number of platelets) or other prescribed medicines (e.g. fluorides, phosphate, iron containing products) speak to your doctor before taking Rennie Dual Action Tablets because it can affect how these medicines work. To maximise the benefit of all medicines being used, take Rennie Dual Action Tablets 1 to 2 hours after taking any other medicines.
- If you are taking any thiazide diuretics (e.g. bendroflumethiazide), which are used to increase urine production, then you should tell your doctor before taking the product because he or she may want to monitor the calcium levels in your blood.

Taking Rennie Dual Action Tablets with food and drink

As with all calcium containing antacid products intake with large amounts of milk or dairy products should be refrained.

Pregnancy and breast-feeding: Ask your doctor or pharmacist for advice before taking any medicine. Rennie Dual Action Tablets can be used during pregnancy if taken as instructed. Rennie Dual Action Tablets can be used while breast-feeding if taken as instructed (see Section 3).

As Rennie Dual Action Tablets provide a substantial amount of calcium in addition to dietary calcium intake pregnant women should strictly limit their use of Rennie Dual Action Tablets 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.

Rennie Dual Action Tablets contains sodium, glucose and sucrose:

This product contains 14mg of sodium (main component of cooking/table salt) in each tablet. This is equivalent to 0.7% of the recommended maximum daily dietary intake of

sodium for an adult, which should be taken into consideration by patients on a sodium restricted diet.

This product also contains 230mg sucrose and about 555.2mg glucose (including from dextrates) per tablet, which should be taken into account in patients with diabetes mellitus.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Moreover glucose and sucrose may be harmful to the teeth.

3. HOW TO TAKE RENNIE DUAL ACTION TABLETS

Always take Rennie Dual Action Tablets exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Adults and children over 12 only: 2 tablets to be chewed, 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 12 tablets in 24 hours.

Rennie Dual Action Tablets can be used during pregnancy and breast feeding if taken as instructed above.

If symptoms persist after 14 days consult your doctor in order to exclude a more serious disease. Prolonged use should be avoided. Do not give to children under the age of 12.

If you take more Rennie Dual Action Tablets 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.

If you forget to take Rennie Dual Action Tablets: Do not take a double dose to make up for a forgotten dose.

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.

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. If you experience these reactions stop treatment immediately and seek medical advice.

Long term use of high doses can cause high blood levels of calcium and magnesium, especially in people with kidney conditions. This can cause nausea and vomiting, upset

stomach, diarrhoea, tiredness, muscular weakness, confusion, increased urine production, increased thirst and dehydration.

Taking Rennie Dual Action with milk or dairy products over a long period of time may cause milk alkali syndrome, which can cause high blood levels of calcium. Specific symptoms of milk alkali syndrome may include impaired sense of taste, headache, kidney problems, fatigue and lumps under the skin.

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 DUAL ACTION TABLETS

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

Do not use this medicine after the expiry date which is stated on the carton and foil after “EXP”. The expiry date refers to the last day of that month.

Do not store above 30°C. Store in the original package in order to protect from moisture.

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 Dual Action Tablets contain:

Each chewable tablet contains the active ingredients calcium carbonate (625mg), magnesium carbonate (73.5mg) and alginic acid (150mg).

The other ingredients are Sodium hydrogen carbonate, sucrose, glucose monohydrate, povidone, talc, magnesium stearate, dextrates, saccharin sodium, lemon cream flavour (contains lemon oil, lime oil, orange oil, l-menthole, vanilline, maltodextrin, gum arabic, ascorbic acid, butylhydroxyanisol), peppermint flavour (contains peppermint oil, maltodextrin, gum arabic, silicon dioxide).

What Rennie Dual Action Tablets look like and contents of the pack:

Rennie Dual Action Tablets are off white, speckled circular chewable tablets, flat on both sides with a bevelled edge.

They are supplied in foil strips in a carton with this leaflet.

The tablets are available in pack-sizes of 12, 18, 24, 30, 36 and 48.

Not all pack sizes may be marketed.

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This leaflet was last revised in September 2022