Package leaflet: Information for the patient

Rennie Orange 680 mg/80 mg chewable tablets
Calcium Carbonate/Magnesium 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 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
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1. What Rennie Orange is and what it is used for

How does Rennie Orange work
Each Rennie Orange chewable tablet contains calcium carbonate and magnesium carbonate, heavy. These relieve symptoms of excess stomach acidity by neutralising the acid in the stomach.

What Rennie Orange is used for
Rennie Orange is used in adults and adolescents 12 years and older, to relieve the symptoms caused by excess stomach acid, such as:
- heartburn,
- acid regurgitation (the backflow of acid from the stomach up into the oesophagus that may cause a sour taste in the mouth),
- stomach pain,
- indigestion.

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

Do not take Rennie Orange if you are/have:
- allergic to calcium carbonate or magnesium carbonate or any of the other ingredients of this medicine (listed in section 6),
- severely reduced kidney function,
- deposits of calcium salts in kidney vessels or in the connective tissues of the kidneys (nephrocalcinosis),
- kidney stones containing calcium (nephrolithiasis),
- an abnormally high level of calcium in your blood (hypercalcaemia) and/or circumstances that lead to hypercalcaemia,
- abnormally low level of phosphate in your blood (hypophosphatemia)

Warnings and precautions
Talk to your doctor or pharmacist before or during taking Rennie Orange if you have:
- Other symptoms, such as persistent stomach ache or kidney pain, contact a doctor to identify any possible organic disorders. Long-term use must be avoided.
- Reduced kidney function. Avoid long-term use and have your blood calcium, magnesium, and phosphate levels checked regularly by a doctor.
- Increased calcium in your urine (hypercalciuria). Avoid taking Rennie Orange.

Regular checks by a doctor of blood calcium, magnesium, and phosphate levels are recommended during prolonged high doses use. Prolonged use of Rennie Orange tablets increases the risk of kidney stones. Do not take Rennie Orange with large amounts of milk or dairy products as this may result in milk-alkali syndrome (a disorder affecting the metabolism of calcium).

Children and adolescents
Rennie Orange is not recommended for children under 12 years.

Other medicines and Rennie Orange
Tell your doctor or pharmacist if you are taking, have recently taken/used or might take/use any other medicines.

This particularly applies to:
- medicines to treat bacterial infections,
- medicines to treat heart weakness,
- levothyroxine: a medicine to treat thyroid hormone deficiency,
- eltrombopag: a medicine to treat a lack of blood platelets, severely reduced number of all blood cells and bleeding disorders,
- medicines to treat reduced bone density,
- dolutegravir: a medicine to treat HIV infection.

Rennie Orange may reduce the absorption of these medicines. They may not work as a result. These medicines should therefore be taken either 1 to 2 hours before or at least 4 hours after Rennie Orange.

Certain medicines to increase water output through your kidneys may reduce the amount of calcium excreted in the urine. Because Rennie Orange contains calcium carbonate, your doctor should monitor the level of calcium in your blood in these circumstances.
Calcium salts reduce the absorption of fluorides and iron. Calcium and magnesium salts may prevent the absorption of phosphates.

Rennie Orange with food and drink
There are no food and drink restrictions related with Rennie Orange intake. However, in case of heartburn, it is generally recommended that you avoid carbonated drinks, caffeine, and alcohol, as this will worsen the symptoms.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may 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 and breast-feeding if taken as recommended in this leaflet. The maximum recommended daily dose should not be exceeded and Rennie Orange should not be taken for more than 2 weeks (see section 3 "How to take Rennie Orange").
Pregnant women should avoid concomitant excessive intake of milk and dairy products in order to prevent calcium overload.

Calcium carbonate and magnesium carbonate, heavy are excreted in human milk. However therapeutic doses of Rennie Orange are not anticipated to effect breastfed newborns/infants.

Driving and using machines
Rennie Orange has no or negligible influence on the ability to drive and use machines.

Rennie Orange contains sucrose and sodium
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine. This medicine contains 475 mg of sugar (sucrose) per chewable tablet. This should be taken into account in patients with diabetes mellitus.
This medicine contains less than 1 mmol sodium (23 mg) per chewable tablet, that is to say essentially "sodium-free".

3. How to take Rennie Orange

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.

The recommended dose for adults and adolescents12 years and older is:
- Chew or suck on 1 or 2 chewable tablets one hour after major mealtimes or when you go to bed.
- If you already have symptoms, you can also take 1 or 2 chewable tablets immediately.
- Do not take more than 11 chewable tablets per day and do not take the product for more than 2 weeks.
- You must talk to a doctor if you do not feel better or if you feel worse after taking the product for 7 days.

Use in children and adolescents
There are no studies regarding the safety and effectiveness of Rennie Orange in children. Rennie Orange is not recommended for children under 12 years of age.

If you take more Rennie Orange than you should
Taking more chewable tablets than recommended for a few months may result in:
- kidney damage,
- increased magnesium blood level,
- increased calcium blood level,
- increased blood pH over 7.43.

Signs of increased calcium blood levels include:
- muscle weakness,
- irregular heartbeat,
- stomach and bowel problems such as loss of appetite, nausea, vomiting, and constipation with painful flatulence,
- confusion may occur with prolonged and severely increased calcium blood levels,
- increased urination with insatiable thirst and dizziness.

Contact your doctor if you have any of these symptoms.

If you forget to take Rennie Orange
Do not take a double dose to make up for a forgotten dose.

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.

The following side effects may occur whereby the frequency cannot be estimated from the available data:

- hypersensitivity reactions have very rarely been reported. Symptoms may include:
  - rash
  - nettle-rash, itching
  - mostly painful severe swelling of deep skin layers, mainly in the face
  - breathing difficulties
  - severe allergic reaction, affecting the whole body
- nausea, vomiting
- stomach discomfort
- constipation, diarrhoea
- muscle weakness
- people with reduced kidney function who take high doses over a prolonged period may experience:
  - increased calcium and magnesium blood levels
  - increased blood pH
  - reduced phosphate blood level
- increased calcium blood level (milk-alkali syndrome) which may be accompanied by
  - headaches
  - nausea, vomiting
  - loss of taste
  - calcium salt deposits in soft tissue of the skin and organs
  - dizziness, weakness
  - increased nitrogen level in the blood called azotaemia

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 Orange

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 pack after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C.
Store in the original package in order to protect from light and 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 Orange contains

- The active substances are calcium carbonate and magnesium carbonate, heavy.
  Each chewable tablet contains 680 mg calcium carbonate (equivalent to 272 mg calcium) and 80 mg magnesium carbonate, heavy (equivalent to 20 mg magnesium).
- The other ingredients are sucrose, potato starch, maize starch, pregelatinized, saccharin sodium, magnesium stearate, talc, paraffin light, liquid, orange flavour.

What Rennie Orange looks like and contents of the pack

The chewable tablets are square (side length of the tablet: 15 mm x 15 mm) and white, debossed with Rennie on both sides. Rennie Orange is packed in blisters. Chewable tablets are in packs of 12, 24, 36, 48, 60, 72, 84, 96, 108 and 120 tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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

Manufacturer:
Delpharm Gaillard
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France

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