Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Rennie Orange 680 mg/80 mg chewable tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Rennie Orange is a combination of the two antacids, 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) as the active substances.

Excipient(s) with known effect: one chewable tablet contains 475 mg of sucrose, see section 4.4.
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Chewable tablet
The chewable tablet is square and white, debossed with RENNIE on both sides. Side length of the tablet is 15mm x 15mm.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

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,
- episodic gastric pain,
- gastric hyperacidity leading to indigestion.

4.2 Posology and method of administration

Posology
Single dose for adults and adolescents ≥ 12 years: 1–2 chewable tablets, maximum daily dose: 11 chewable tablets.
To be taken by chewing or sucking one hour after main mealtimes, at bedtime, or in case of acute symptoms.
The maximum daily dose must not be exceeded and should not be taken continuously for longer than two weeks.
For use with renal impairment: see sections 4.3 and 4.4.

Paediatric population
No safety and efficacy studies are available for children; use is not recommended for children under 12 years of age.

Method of administration
For oral use. The tablets are to be chewed or sucked. No water is required.

4.3 Contraindications

This medicine must not be administered in the following cases:

- Hypersensitivity to the active substances or to any of the excipients listed in section 6.1,
- Severe renal insufficiency,
- Hypercalcemia and/or states that result in hypercalcemia,
- Nephrolithiasis due to calculi containing calcium deposits,
- Hypophosphatemia.

4.4 Special warnings and precautions for use

- Long-term use must be avoided. In case of pain persisting over a prolonged period (more than two weeks), it is recommended that medical attention should be sought so that any potential organic disease can be identified.
- Long-term use should be avoided in patients with renal impairment. Caution should be exercised in patients with mild to moderate impairment of renal function. If Rennie Orange is used in such patients, plasma calcium, phosphate and magnesium levels should be regularly monitored.
- Rennie Orange should not be taken by anyone with existing hypercalciuria.
- The development of hypercalcemia, hypermagnesemia, and hypophosphatemia must be considered with the long-term use of high doses. Prolonged use of Rennie Orange increases the risk of renal calculi. Rennie Orange must not be taken with large amounts of milk or dairy products (Burnett's syndrome).

Information about excipients
This medicine contains 475 mg of sucrose per chewable tablet. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption, or sucrase-isomaltase insufficiency should not take this medicine. This should also be considered by diabetic patients.
This medicine contains less than 1 mmol sodium (23 mg) per chewable tablet, that is to say essentially 'sodium-free'.

4.5 Interaction with other medicinal products and other forms of interaction

- Due to the potential for reduced absorption, two hours should generally be left between taking antacids and other medications, such as antibiotics (e.g. tetracyclines, quinolones), cardiac glycosides (e.g. digoxin), levothyroxine, eltrombopag, bisphosphonates and dolutegravir.
- Taking antibiotics in the quinolone group at the same time as Rennie Orange reduces the absorption of these antibiotics. They may not work as a result. These antibiotics should therefore be taken either 1–2 hours before or at least 4 hours after Rennie Orange.
- Calcium salts reduce the absorption of fluorides and products containing iron; calcium salts and magnesium salts may prevent the absorption of phosphates.
- Thiazide diuretics reduce calcium elimination. When Rennie Orange is co-administered with thiazides, serum calcium levels should therefore be monitored.

Therefore, it is preferable to administer the antacid separately from other drugs, allowing a 1–2 hours interval.

4.6 Fertility, pregnancy and lactation

Pregnancy
The animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity related with the administration of the medicinal product Rennie Orange. No increased risks for congenital defects are anticipated, neither have they been observed after the long-term use of calcium carbonate and magnesium carbonate during pregnancy.
Rennie Orange could be used during pregnancy if taken as labelled. The maximum recommended daily dose should not be exceeded and Rennie Orange should not be taken for more than 2 weeks (see section 4.2).
During pregnancy and lactation, it has to be taken into account that the tablets provide a substantial amount of calcium in addition to dietary calcium intake. For this reason, pregnant women should avoid concomitant, excessive intake of milk and dairy products. This warning is to prevent calcium overload which might result in milk-alkali syndrome.

Breast-feeding
Calcium carbonate and magnesium carbonate, heavy are excreted in human milk, but at therapeutic doses of Rennie Orange no effects on the breastfed newborns/infants are anticipated.

Fertility
No data available.

4.7 Effects on ability to drive and use machines

Rennie Orange has noor negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Immune System Disorders
Hypersensitivity reactions have very rarely been reported. Symptoms may include rash, urticaria, pruritus, angioedema, dyspnea and anaphylaxis.

Gastrointestinal Disorders
Nausea, vomiting, stomach discomfort, constipation and diarrhea may occur.

Musculoskeletal and Connective Tissue Disorders
Muscular weakness may occur.

Metabolism and Nutrition Disorders
Renal impairment and prolonged use of high doses may result in hypercalcemia, hypermagnesemia, metabolic alkalosis with gastric symptoms, muscle weakness, and depleted phosphate.

Burnett syndrome (milk-alkali syndrome, a disorder of calcium metabolism) may be accompanied by headaches, nausea, vomiting, ageusia, calcinosis, dizziness, asthenia, and azotemia.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance; Website: www.hpra.ie.

4.9 Overdose

Especially in patients with renal impairment, prolonged use (over several months) of high doses of calcium carbonate and magnesium carbonate may result in hypercalcemia, hypermagnesemia, metabolic alkalosis, and renal failure.
Hypercalcemia may present clinically in the form of myasthenia, gastrointestinal symptoms (constipation, nausea, and vomiting), and cardiac arrhythmias, as well as in the form of clouding of consciousness after prolonged and severed hypercalcemia. Hypercalcemia may when appropriate be treated with rehydration, infusion of isotonic saline solution, and forced diuresis.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Drugs for acid related disorders, Antacids, ATC code: A02AD01

The antacid action of calcium and magnesium carbonate is based on the neutralization of gastric acid. Calcium carbonate results in rapid neutralization. Combination with magnesium carbonate potentiates this effect as magnesium carbonate itself exhibits a high neutralization potential. The effective buffer capacity is between pH 5.5 and 6.5 for calcium carbonate and between pH 6.5 and 7.5 for magnesium carbonate. After an oral dose of two chewable tablets on an empty stomach, an increase in pH of more than one unit occurs within 5 minutes.
Studies have shown that calcium carbonate antacids have upon-contact (immediate) onset of acid neutralization, with clinically relevant pH change occurring within minutes.
In vitro acid neutralization studies (artificial stomach model) showed that Rennie Orange increases stomach pH from pH 1.5–2 to pH 3 in 40 seconds and is able to reach pH 4 in 1 minute 13 seconds. The maximum level of pH achieved in the model was pH 5.24.

5.2 Pharmacokinetic properties

Calcium and magnesium carbonate react with the excess acid in the stomach to produce water and soluble chlorides. These in turn react with intestinal, biliary and pancreatic secretions, in which they form insoluble salts that are excreted in the feces. Less than 10% of the calcium and 15–20% of the magnesium is absorbed and is eliminated rapidly via the kidneys in healthy individuals.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, toxicity to reproduction and development.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose
Potato starch
Maize starch, pregelatinized
Saccharin sodium
Magnesium stearate
Talc
Paraffin, light liquid
Orange flavour

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years

6.4 Special precautions for storage

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

6.5 Nature and contents of container

Folding carton containing 12, 24, 36, 48, 60, 72, 84, 96, 108, 120 chewable tablets in PVC/aluminium blister packs.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Bayer Limited
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Stillorgan
Co Dublin
A94 H2K7
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8 MARKETING AUTHORISATION NUMBER

PA1410/094/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 23rd October 2026

10 DATE OF REVISION OF THE TEXT