1. NAME OF THE MEDICINAL PRODUCT

Rennie Spearmint, chewable tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Per chewable tablet 680 mg calcium carbonate and 80 mg magnesium carbonate.
Excipients: each chewable tablet contains 400 mg sorbitol.
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Chewable tablets.

Rennie Spearmint is a creamy white, square tablet with rounded edges and the inscription "RENNIE" embossed on both sides; the tablet has a spearmint aroma.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Relief of hyperacidity and heartburn.

4.2 Posology and method of administration

Posology

For adults and children over the age of 12 years:
1-2 Rennie Spearmint chewable tablets at a time, as needed, preferably to be taken about one hour after a meal and before going to bed. For the treatment of heartburn, an additional 1 -2 tablets may be taken between those times. The maximum daily dose of 10 tablets must not be exceeded. The patient must be advised to consult a doctor if symptoms persist for longer than 14 days.
It is advisable to wait roughly 1 -2 hours between taking other medicines and taking Rennie.

Paediatric patients:
Only for use by adults and children over the age of 12 years. The safety and efficacy in children aged under 12 years have not yet been established.

Method of administration:For oral use. The tablets can be chewed or sucked. The tablets can be taken without water.

As with all antacids, if symptoms persist, diagnostic measures are recommended to rule out serious diseases.

For special warnings and precautions for use, see section 4.4.

4.3 Contraindications

- Hypersensitivity to any of the active substances or to any of the excipients listed in section 6.1.
- Severe renal impairment, hypercalcaemia and/or conditions resulting in hypercalcaemia.
- Pre-existing hypophosphataemia.
- Nephrolithiasis due to calculi containing calcium.

4.4 Special warnings and precautions for use

Prolonged use should be avoided.
If the symptoms persist or only partially disappear, further medical investigation is necessary.
As is the case with other antacids, Rennie Spearmint may mask a malignancy in the stomach.
Rennie Spearmint must not be used in the following cases:

- Hypercalciuria.
- Caution should generally be exercised in patients with renal dysfunction.

If Rennie Spearmint is used in these patients, plasma levels of calcium, phosphate and magnesium should be monitored regularly.

In general, antacids containing calcium must be used with caution in patients with constipation, haemorrhoids and sarcoidosis.
Prolonged use of high dosages can lead to undesirable side effects, such as hypercalcaemia, hypermagnesaemia and milk-alkali syndrome, particularly in patients with renal impairment. The product must not be taken with large quantities of milk (or milk products).
Prolonged use increases the risk of kidney stones developing.
Rennie contains 400 mg sorbitol per tablet and is unsuitable for patients with a sorbitol intolerance. Patients with rare hereditary conditions such as fructose intolerance should not use this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

Changes in the acidity of the gastric juice, such as those brought about by taking antacids, can have consequences for the extent and rate of absorption of medicinal products administered concomitantly.
It has been demonstrated that antacids containing calcium and magnesium can hinder the absorption of some antibiotics (such as tetracyclines and quinolones), cardiac glycosides (including digoxin), bisphosphonates, dolutegravir, levothyroxine and eltrombopag due to the formation of complexes.
Calcium salts reduce the absorption of fluoride and products containing iron, and calcium salts and magnesium salts can hinder the absorption of phosphates.
Thiazide diuretics reduce the urinary excretion of calcium. Due to an increased risk of hypercalcaemia, serum calcium levels must be monitored regularly during concomitant use of thiazide diuretics.
It is recommended that antacids should not be taken at the same time as these medicinal products, but that antacids should be taken 1-2 hours afterwards.

Effects on laboratory parameters:
The use of antacids can interfere with physiological values: urinary pH may increase and the serum concentration of phosphates and potassium may decrease as a result of excessive and prolonged use.

4.6 Fertility, pregnancy and lactation

Pregnancy
No increased risk of congenital defects has been observed following the use of calcium carbonate and magnesium carbonate during pregnancy. Rennie Spearmint can be used as directed during pregnancy. Do not exceed the maximum recommended dose and do not use for longer than 2 weeks, see section 4.2.

Pregnant women must avoid excessive consumption of milk (or milk products). The purpose of this warning is to avoid excessive intake of calcium (which can lead to milk-alkali syndrome).

Lactation
Calcium and magnesium are excreted in human milk, but at therapeutic doses no effects on newborns are anticipated. Rennie Spearmint can be used as directed while breast-feeding.

Fertility
There are no indications that Rennie has an adverse effect on fertility at the recommended dose.

4.7 Effects on ability to drive and use machines
Rennie Spearmint has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects
Immune system disorders:
Very rarely, hypersensitivity reactions have been reported. The clinical symptoms were rash, urticaria, pruritus, angioedema, dyspnoea and anaphylaxis.

Metabolism and nutrition disorders:
Prolonged use of high doses may possibly lead to hypermagnesaemia or hypercalcaemia (may be accompanied by gastrointestinal symptoms and muscle weakness (see below), fatigue, confusion, polyuria, polydipsia and dehydration) and alkalosis, particularly in patients with renal dysfunction.

Gastrointestinal disorders:
Nausea, vomiting, stomach problems, constipation, and diarrhoea can occur.

Musculoskeletal and connective tissue disorders:
Muscle weakness can occur.

4.8.1 Undesirable effects only occurring with milk-alkali syndrome (see 4.9):

Gastrointestinal disorders:
Ageusia can occur with milk-alkali syndrome.

General disorders and administration site conditions:
Calcinosis and asthenia can occur with milk-alkali syndrome.

Nervous system disorders:
Headache can occur with milk-alkali syndrome.

Renal and urinary disorders:
Azotaemia can occur with milk-alkali syndrome.

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form https://sideeffects.health.gov.il

4.9 Overdose

Particularly in patients with impaired renal function, prolonged intake of high doses of calcium carbonate and magnesium carbonate can lead to renal insufficiency, hypermagnesaemia, hypercalcaemia and alkalosis, which can result in digestive symptoms (nausea, vomiting, constipation) and muscle weakness. In these cases, stop administration and drink plenty of fluids. In severe cases of overdose (including milk-alkali syndrome), a doctor must be consulted because other measures may be necessary for rehydration (including infusion).

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: antacids, other combinations, ATC code: A02 AX.

Mechanism of action

Rennie Spearmint is a combination of two antacids, calcium carbonate and magnesium carbonate. The mechanism of action of calcium carbonate and magnesium carbonate is local, based on the neutralisation of gastric acid, and is not dependent on systemic absorption.

Pharmacodynamic effects

Calcium carbonate has a rapid, long-lasting and potent neutralising effect. This effect is increased by the addition of magnesium carbonate, which also has a potent neutralising effect. In-vitro studies (with an artificial human stomach model) demonstrate that Rennie increases the pH of the study from 1.5-2.0 to pH 3.0 in 40 seconds and to pH 4.0 in 1 minute and 13 seconds. The maximum pH in this model was pH 5.24.

Clinical efficacy and safety

In healthy volunteers, a significant increase in the pH of the contents of the stomach was reached within 2 minutes following the administration of calcium carbonate and magnesium carbonate. The total neutralising capacity of 2 tablets is 29 mEq/H^+ (titration to endpoint pH 2.5).

5.2 Pharmacokinetic properties

Calcium and magnesium:

In the stomach, calcium carbonate and magnesium carbonate react with the acid in gastric juice to form water and soluble mineral salts.

$CaCO_3 + 2\ HCl \rightarrow CaCl_2 + H_2O + CO_2$

$MgCO_3 + 2\ HCl \rightarrow MgCl_2 + H_2O + CO_2$

Calcium and magnesium can be absorbed from these soluble salts. However, the extent of absorption is dependent on the patient and the dose. Less than 10% calcium and 15-20% magnesium is absorbed.

The small quantities of calcium and magnesium absorbed are usually rapidly excreted via the kidneys in healthy individuals. In patients with renal dysfunction, serum concentrations of calcium and magnesium may be elevated.

Due to the effects of various digestive juices outside the stomach, the soluble salts are converted to insoluble salts in the intestinal tract and then excreted with the faeces.

5.3 Preclinical safety data

No special data known.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Rennie Spearmint contains the following excipients per chewable tablet: sorbitol, talc, pregelatinised maize starch, potato starch, magnesium stearate, light liquid paraffin, spearmint flavouring and saccharin sodium.

6.2 Incompatibilities

None.

6.3 Shelf life

The expiry date of the product is indicated on the packaging materials.

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

Box containing 48, 60, and 96 chewable tablets in PVC/aluminium blister strips.

Not all pack sizes may be marketed.

6.6 Instructions for use and handling

No special requirements.

7. MARKETING AUTHORISATION HOLDER

Bayer Israel Ltd., 36 Hacharash Street, Hod Hasharon.

Revised in June 2022 according to MoH guidelines