SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Rennie Spearmint

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Calcium Carbonate	680.0 mg
Heavy Magnesium Carbonate	80.0 mg

Also contains glucose and sucrose
For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Chewable Tablets
A square cream white tablet with rounded corners, bevelled edges and concave faces, engraved 'Rennie' on both sides.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

For the relief of indigestion, heartburn, nervous indigestion, hyperacidity, flatulence, gastritis, upset stomach, dyspepsia, biliousness, overindulgence in food and drink, indigestion during pregnancy.

4.2 Posology and method of administration

Posology:
Tablets to be taken orally, sucked or chewed.

Adults and Children over 12 years:
Two tablets to be sucked or chewed as a single dose, preferably to be taken one hour after meals and before going to bed but also in between in case of heartburn or gastric pain. A maximum daily dose of 8 g calcium carbonate, corresponding to 10 tablets a day, must not be exceeded.

Children
Not recommended for children under 12 years of age.

As with all antacids, if symptoms persist despite 14 days of continuous therapy, diagnostic measures are strongly recommended in order to rule out a more serious disease.

4.3. Contraindications

Rennie should not be administered to patients with:

- Hypersensitivity to any of the ingredients of the product
- Hypercalcaemia and/or conditions resulting in hypercalcaemia
- Nephrolithiasis due to calculi containing calcium deposits
- Severe renal insufficiency
- Hypophosphataemia

4.4 Special warnings and precautions for use

- Prolonged use should be avoided.

- The stated dose should not be exceeded. If, after 14 days of treatment, symptoms persist or only partly disappear the patient should consult a doctor.

- Caution should be exercised in patients with mild to moderate impairment of renal function (see section 4.3 – contraindication in severe renal insufficiency). If Rennie is used in such patients, plasma calcium, phosphate and magnesium levels should be regularly monitored.

- Long term uses at high doses can result in undesirable effects such as hypercalcaemia, hypermagnesaemia and milk-alkali syndrome, especially in patients with renal insufficiency.

- Rennie should not be used in patients with hypercalciuria (see also section 4.3). Prolonged use increases the risk of formation of renal calculi.

- This product should not be taken with large amounts of milk or dairy products.

- Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

Changes in gastric acidity, such as that caused by the ingestion of antacids, can affect the rate and degree to which some concurrently administered medicines are absorbed.

- It has been shown that antacids which contain calcium or magnesium may form complexes with certain substances e.g., antibiotics (such as tetracyclines and quinolones), and cardiac glycosides (e.g. digoxin), levothyroxine, and eltrombopag, resulting in decreased absorption. This should be borne in mind when concomitant administration is considered.

- Calcium salts reduce the absorption of fluorides and iron-containing products, 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 should be regularly monitored during concomitant use of thiazide diuretics.

Therefore it is preferable to take the antacid separately from other drugs, allowing at least 4 hours before or after taking eltrombopag and a 1-2 hour interval for all other drugs.

4.6. Fertility, pregnancy and lactation

No increased risk of congenital defects has been observed after the use of this product during pregnancy and it can be used during pregnancy and lactation if taken as instructed but prolonged intake of high dosages should be avoided. Pregnant women should limit the use of these products to the maximum recommended daily doses (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 strictly limit their use of tablets to the maximum recommended daily dose and avoid concomitant, excessive intake of milk and dairy products. This warning is to prevent calcium overload which might result in milk-alkali syndrome.

4.7 Effects on ability to drive and use machines

No effects on ability to drive and use machines have been observed.

4.8 Undesirable effects

The listed adverse drug reactions are based on spontaneous reports, thus an organisation according to CIOMS III categories of frequency is not possible.

Immune System Disorders:

Hypersensitivity reactions have very rarely been reported. Clinical symptoms may include rash, urticaria, angioedema and anaphylaxis.

Metabolism and Nutrition Disorders:

Especially in patients with impaired renal function, prolonged use of high doses can result in hypermagnesaemia or hypercalcaemia and alkalosis which may give rise to gastric symptoms and muscular weakness (see below).

Gastrointestinal Disorders:
Nausea, vomiting, stomach discomfort and diarrhoea may occur.

Musculoskeletal and Connective Tissue Disorders:
Muscular weakness may occur.

Undesirable effects occurring in the context of milk-alkali syndrome (see 4.9):

Gastrointestinal Disorders:
Ageusia may occur in the context of milk-alkali syndrome.

General Disorders and Administration Site Conditions:
Calcinosis and asthenia may occur in the context of milk-alkali syndrome.

Nervous System Disorders:
Headache may occur in the context of milk-alkali syndrome.

Renal and Urinary Disorders:
Azotemia may occur in the context of milk-alkali syndrome.

Reporting of suspected adverse reactions
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. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

4.9 Overdose

Especially in patients with impaired renal function, prolonged use of high doses of calcium carbonate and magnesium carbonate can result in renal insufficiency, hypermagnesaemia, hypercalcaemia and alkalosis which may give rise to gastrointestinal symptoms (nausea, vomiting, constipation) and muscular weakness. In these cases, the intake of the product should be stopped and adequate fluid intake encouraged. In severe cases of overdosage (e.g. milk-alkali syndrome), a health care professional must be consulted because other measures of rehydration (e.g. infusions) might be necessary.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic Classification: Antacids
ATC codes:
Calcium carbonate: A02AC01
Magnesium carbonate: A02AA01

Calcium and magnesium carbonates react with excess acid in the gastric juice to produce soluble chlorides.
$CaCO_3 + 2HCl \Rightarrow CaCl_2 + H_2O + CO_2$
$MgCO_3 + 2HCl \Rightarrow MgCl_2 + H_2O + CO_2$

Calcium carbonate has a rapid and powerful neutralising action. This effect is increased by the addition of magnesium carbonate which also has a strong neutralising action.

In healthy volunteers, a significant increase in the pH of stomach contents above baseline pH was achieved between 1 and 6 minutes after dosing.

5.2. Pharmacokinetic properties

A small amount of calcium and magnesium may be absorbed, but in healthy subjects is usually rapidly excreted by the kidney.

The soluble chlorides produced by the reaction of calcium and magnesium with gastric acid react, in turn, with intestinal, biliary and pancreatic secretions to form insoluble salts, which are excreted in the faeces.

5.3. Preclinical safety data

There is no information of relevance to the safety assessment in addition to what is stated in other parts of the Summary of Product Characteristics.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Sucrose
Glucose
Talc
Polyvidone (povidone)
Spearmint Flavour
Magnesium Stearate
Saccharin Sodium

6.2. Incompatibilities

None.

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store below 25 °C. Store in the original package.

6.5 Nature and contents of container

Tablets are packed in a hard tempered aluminium foil (20µm)/clear thermoformable PVC (150µm) bubble pack, with six or twelve tablets per strip. 1, 2, 3, 4, 8, 10 or 12 strips are packed in a cardboard carton.

12 Tablet Pocket Pack – Tablets are packed in hard tempered aluminium foil (20µm)/clear thermoformable PVC (250µm) bubble pack, with six tablets per strip. Two strips are packed in a cardboard pocket pack.

12 tablet pack - tablets are roll wrapped in laminated foil consisting of aluminium foil (7µm) externally, then polythene (12gsm), bleached kraft paper (37gsm), and polythene (12gsm) internally.

3 roll wraps of 12 tablets may also be packed into a blister card to contain 36 tablets
Pack sizes: 6, 12, 24, 36, 48, 72, 96, 120, 144 tablets.

6.6 Special precautions for disposal

None.

7 MARKETING AUTHORISATION HOLDER

Bayer plc
400 South Oak Way

Reading
RG2 6AD

8. MARKETING AUTHORISATION NUMBER(S)

PL 00010/0361

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1st July 2005

10 DATE OF REVISION OF THE TEXT

01/02/2018