

# SUMMARY OF PRODUCT CHARACTERISTICS

## 1 NAME OF THE MEDICINAL PRODUCT

Rennie Deflatine  
Rennie Heartburn, Indigestion and Wind Relief 680mg/80mg/25mg Chewable  
Tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Calcium Carbonate	680.0 mg (272 mg elemental Calcium)
Magnesium Carbonate, heavy	80.0 mg (20 mg elemental Magnesium)
Simeticone	25.0 mg

Excipient with known effect: Sorbitol (E420) 430mg per tablet.  
For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Chewable Tablet  
Cream white flat round tablet, scored on one side.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic indications

For the effective relief of acid indigestion, nervous indigestion, heartburn, upset stomach, uncomfortable bloating, biliousness, flatulence, painful trapped wind, and indigestion and heartburn during pregnancy.

### 4.2 Posology and method of administration

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

#### Adults and children over 12 years

One or two tablets to be sucked or chewed as required. A maximum daily dose of 8g calcium carbonate, corresponding to 11 tablets a day, must not be exceeded.

#### Children

Not recommended for children under 12 years.

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.
- This product contains 430mg sorbitol per tablet and may be unsuitable for people with sorbitol intolerance. Patients with rare hereditary problems of fructose intolerance, 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), bisphosphonates, dolutegravir, 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**

### *Pregnancy*

Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity.

No increased risks of congenital defects have been observed after the use of this product during pregnancy.

This medicine can be used during pregnancy if taken as instructed.

The maximum recommended daily dose should not be exceeded and should not be taken for more than 2 weeks. If symptoms persist or only partly disappear after 2 weeks, medical advice should be sought.

In order to prevent calcium overload, pregnant women should avoid concomitant excessive intake of milk and dairy products (1 litre of milk contains up to 1.2 g elemental calcium).

### *Breastfeeding*

Calcium and magnesium are excreted in human milk, but at therapeutic doses of the product no effects on the breastfed newborns/infants are anticipated.

Simeticone is not absorbed from the intestinal tract. Therefore, it cannot be excreted in breast milk.

This medicine can be used during breastfeeding.

### *Fertility*

There is no known evidence suggestive that at recommended dose this medicine has adverse effects on human fertility.

#### **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, pruritus, angioedema, difficulty in breathing 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, constipation and diarrhoea may occur.

Musculoskeletal and Connective Tissue Disorders:

Muscular weakness may occur.

#### **Undesirable effects occurring in the context of milk-alkali syndrome (see section 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](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

#### **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.

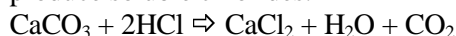
### **5 PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamic properties**

Pharmacotherapeutic Classification: Antacids, other combinations; ATC code: A02AX

ATC codes: Calcium carbonate: A02AC01  
Magnesium carbonate: A02AA01  
Silicones: A03AX13

Calcium and magnesium carbonates react with excess acid in the gastric medium to produce soluble chlorides.



Each Rennie Deflatine tablet neutralises 15.5 mEq H<sup>+</sup>

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.

Simethicone is an antifoaming agent. In the stomach it causes gas bubbles to coalesce and disperse, thus liberating any trapped gas.

#### **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.

Simethicone is not systemically absorbed and is pharmacologically inert.

### **5.3 Preclinical safety data**

Preclinical studies on this medicine are not available. The available preclinical data on calcium carbonate and magnesium carbonate based on studies of repeated dose toxicity, genotoxicity and or carcinogenic potential, and toxicity to reproduction revealed no specific hazard at therapeutic doses for humans.

The available data on pharmacokinetics and toxicology of simeticone show no evidence of bioavailability after oral administration in animals.

## **6 Pharmaceutical particulars**

### **6.1 List of Excipients**

Sorbitol, Purified talc, pregelatinised maize starch, Potato starch, Magnesium stearate, Mint flavour, Lemon flavour, Purified water (not detectable).

### **6.2 Major incompatibilities**

None.

### **6.3 Shelf life**

3 years

### **6.4 Special precautions for storage**

Do not store above 25°C.

### **6.5 Nature and contents of container**

12 tablets are packed into blister strips comprising of 150um pvc film and 20um aluminium foil (60gsm). The strips are then packed into cardboard cartons to contain 12, 24, 36, 48, 60, or 96 tablets

2, 4 or 6 tablets may also be packed into strips of 30um aluminium foil coated on the inside with polythene 30gsm. The strips are packed in cardboard cartons to contain 2, 4, 6, 12, 16, 18, 20, 24, 30, 36, 42 & 48 tablets

Pack sizes: 2, 4, 6, 12, 16, 18, 20, 24, 30, 36, 42, 48, 60, 96

### **6.6 Special precautions for disposal**

No special precautions necessary.

**7     MARKETING AUTHORISATION HOLDER**

Bayer plc  
400 South Oak Way  
Reading  
RG2 6AD

**8     MARKETING AUTHORISATION NUMBER(S)**

PL 00010/0350

**9     DATE OF FIRST AUTHORISATION/RENEWAL OF THE  
AUTHORISATION**

19/10/2005

**10    DATE OF REVISION OF THE TEXT**

09/11/2022