

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Rennie Deflatine Chewable Tablets Calcium Carbonate 680mg Magnesium Carbonate 80mg Simeticone 25mg

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each chewable tablet contains:

Calcium carbonate 680 mg (272 mg elemental calcium)

Magnesium Carbonate, heavy 80 mg

Simeticone 25 mg

Excipients: Contains Sorbitol (E420) 430mg

For a full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Chewable tablet

A white, circular, flat tablet, with bevelled edges and a single score line on one surface.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic Indications

For the effective relief of acid indigestion, heartburn, uncomfortable bloating, flatulence and painful trapped wind.

### 4.2 Posology and method of administration

Posology:

To be taken orally sucked or chewed.

Adults: One or two tablets to be sucked or chewed as required, to a maximum of eleven tablets a day.

Doses of 8-11 tablets should not be continued for more than a few days.

Children and adolescents: Not recommended for use in children and adolescents below age 18 due to a lack of sufficient data on safety or efficacy.

### 4.3 Contraindications

Rennie Deflatine should not be administered in the following cases:

- Hypersensitivity to any of the ingredients of the product
- Hypercalcaemia, hypercalciuria and/or conditions resulting in hypercalcaemia e.g. sarcoidosis
- Nephrolithiasis due to calculi containing calcium deposits
- Severe renal insufficiency
- Hypophosphatemia

### 4.4 Special warnings and precautions for use

Prolonged use should be avoided. Do not exceed the stated dose and if symptoms persist after 7 days, further medical advice should be sought.

Caution should generally be exercised in the case of patients with impaired renal function. If Rennie Deflatine is to be used in these patients, plasma calcium, phosphate and magnesium levels should be regularly monitored.

As with other antacids, Rennie Deflatine tablets may mask a malignancy in the stomach.

Long term use at high doses can result in undesirable effects such as hypercalcaemia, hypermagnesaemia and milk-alkali syndrome, especially in patients with renal insufficiency. The product should not be taken with large amounts of milk or dairy products.

Prolonged use possibly enhances the risk for the development of kidney stones.

Patients with rare hereditary problems of fructose intolerance should not take this medicine.

Magnesium salts may cause central nervous system depression in the presence of renal insufficiency.

#### **4.5 Interaction with other medicinal products and other forms of interactions**

Changes in gastric acidity, e.g. during treatment with antacids, may impair the rate and degree of absorption of other drugs, if taken concomitantly.

- It has been shown that antacids containing calcium and magnesium may form complexes with certain substances, e.g. antibiotics (tetracyclines, 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.
- 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.
- Calcium and magnesium salts can also impede the absorption of phosphates, fluorides, and iron containing products.

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

#### **4.6 Fertility, pregnancy and lactation**

No increased risk of congenital defects has been observed after the use of calcium carbonate and magnesium carbonate during pregnancy. In case of high or prolonged doses or renal insufficiency, the risk for hypercalcaemia and/or hypermagnesaemia can not be completely excluded.

Rennie Deflatine tablets can be used during pregnancy if taken as instructed but prolonged intake of high dosages should be avoided. Rennie Deflatine tablets can be used during lactation if taken as instructed.

During pregnancy and lactation, it has to be taken into account that Rennie Deflatine tablets provide a substantial amount of calcium in addition to dietary calcium intake. For this reason, pregnant women should strictly limit their use of Rennie Deflatine chewable tablets to the maximum recommended daily dose (see section 4.2) 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**

None.

#### **4.8 Undesirable effects**

The listed adverse drug reactions are based on spontaneous reports, thus an organization 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 diarrhea may occur.

### **Musculoskeletal and Connective Tissue Disorders**

Muscular weakness may occur.

### **Undesirable effects only 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 HPRC Pharmacovigilance; Website: [www.hpra.ie](http://www.hpra.ie).

## **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 group: Antacids, other combinations; ATC code: A02AX

ATC-Codes: Calcium carbonate A02ACA1, magnesium carbonate A02AA01, silicones A03AX13

Rennie Deflatine is a combination of two antacids, calcium carbonate and magnesium carbonate, as well as simeticone, an antifoaming agent. The latter active ingredient causes gas bubbles to coalesce and disperse, thus liberating any trapped gas.

The mode of action of calcium carbonate & magnesium carbonate is local, based on the neutralisation of gastric acid, and is not dependent on systemic absorption. Calcium carbonate has a rapid, long-lasting and powerful neutralising action. This effect is increased by the addition of magnesium carbonate which also has a strong neutralising action. In vitro, the total neutralising capacity of the product is 16 mEq H<sup>+</sup> (titration to endpoint pH 2.5)

### **5.2 Pharmacokinetic properties**

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



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

The small quantities of calcium and magnesium absorbed are usually excreted rapidly via the kidneys in healthy individuals. In case of impaired renal function, plasma concentrations of calcium and magnesium may be increased.

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

Simeticone is not systemically absorbed and is pharmacologically inert.

### **5.3 Preclinical safety data**

Not applicable.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Sorbitol (E420)

Talc

Pregelatinised maize starch

Potato starch

Magnesium stearate

Mint flavour

Lemon flavour

### **6.2 Incompatibilities**

Not applicable.

### **6.3 Shelf life**

3 years

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

Store below 25°C

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

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

Not all pack sizes may be marketed.

### **6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product**

No special requirements.

**7 MARKETING AUTHORISATION HOLDER**

Bayer Limited  
The Atrium  
Blackthorn Road  
Dublin 18  
Ireland

**8 MARKETING AUTHORISATION NUMBER**

PA1410/051/001

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

Date of first authorization: 16 May 1994

Date of last renewal: 16 May 2009

**10 DATE OF REVISION OF THE TEXT**

May 2020