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 (20 mg elemental magnesium)
Simeticone 25 mg

Excipientswith known effect: Each chewable tablet also contains Sorbitol (E420) 430mg

For the 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.

The maximum daily dose of 8 g calcium carbonate (corresponding to 11 Rennie Deflatine tablets) should not be exceeded and should not be taken continuously for longer than 2 weeks.

Prolonged use should be avoided. If symptoms persist after 7 days, further medical advice should be sought.

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

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

Method of administration
For oral use.

4.3 Contraindications

Rennie Deflatine should not be administered in the following cases:

- Hypersensitivity to the active substances or to any of the excipients listed in section 6.1
- 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 interaction

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, bisphosphonates, dolutegravir, 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

Pregnancy
Animal studies do not indicate reproductive toxicity (see section 5.3).
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 cannot be completely excluded.
Rennie Deflatine tablets 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 (see section 4.2).
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. In order to prevent calcium overload, pregnant women should 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.
Breastfeeding
Calcium and magnesium are excreted in human milk, but at therapeutic doses of Rennie Deflatine no effects on the breastfed newborns/infants are anticipated.

Simethicone is not absorbed from the intestinal tract. Therefore, it cannot be excreted in breast milk.
Rennie Deflatine tablets can be used during breastfeeding if taken as instructed.
Fertility
There is no known evidence suggestive that at recommended dose Rennie has adverse effects on human fertility.

4.7 Effects on ability to drive and use machines

Rennie Deflatine has no influence on the ability to drive and use machines.

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, dyspnea 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.

Gastrointestinal Disorders
Nausea, vomiting, stomach discomfort, constipation 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 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 HPRA Pharmacovigilance; Website: 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. Studies have shown that calcium carbonate antacids have upon-contact (immediate) onset of acid neutralisation, with clinically relevant pH change occurring within minutes.

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.

$CaCO_3 + 2HCl => CaCl_2 + H_2O + CO_2$
$MgCO_3 + 2HCl => MgCl_2 + H_2O + CO_2$

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

Preclinical studies on Rennie Deflatine are not available. The available preclinical data on calcium carbonate and magnesium carbonate based on conventional 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 simethicone show no evidence of bioavailability after oral administration in animals.

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 30 microgram 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 and other handling

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Bayer Limited
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8 MARKETING AUTHORISATION NUMBER

PA1410/051/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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Date of last renewal: 16 May 2009

10 DATE OF REVISION OF THE TEXT

November 2022