Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Rennie ICE 680 mg/ 80 mg Chewable Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each chewable tablet contains:
Calcium carbonate 680 mg (272 mg elemental calcium)
Heavy Magnesium Carbonate 80 mg

Excipient(s) with known effect:
Sucrose 475 mg

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Chewable Tablet.
Creamy white square tablets with occasional slight speckling with concave surfaces engraved ‘Rennie’ on both faces with odour of mint.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For relief of stomach upsets due to hyperacidity and heartburn.

4.2 Posology and method of administration

Tablets 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.

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

Elderly persons:
No special dosage regimen is required, but care should be taken to observe the contraindications and warnings.

4.3 Contraindications

Rennie ICE 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 ICE is to be used in these patients, plasma calcium, phosphate and magnesium levels should be regularly monitored.
As with other antacids, Rennie ICE tablets may mask a malignancy in the stomach.

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. 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, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take Rennie ICE.

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

During pregnancy and lactation, it has to be taken into account that Rennie ICE 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 ICE 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 pertinent.

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 hypermagnesemia 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 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, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@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, hypermagnesemia, hypercalcemia 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 Code: Calcium carbonate A01AC01, magnesium carbonate: A02AA01

Rennie ICE is a combination of two antacids, calcium carbonate and magnesium carbonate. The mode of action of calcium carbonate & magnesium carbonate is local, based on the neutralisation of gastric acid, and is not dependant 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 15.5 mEq H+ (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.

$CaCO_3 + 2HCl \Rightarrow CaCl_2 + H_2O + CO_2$
$MgCO_3 + 2HCl \Rightarrow MgCl_2 + H_2O + CO_2$

Calcium and magnesium can be absorbed from these soluble salts. However, the degree of absorption is dependant 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 the case of impaired renal function, plasma concentrations of calcium and magnesium may be increased.

Due to the effects 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.

5.3 Preclinical safety data

No additional information.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose
Maize starch, pregelatinised
Potato starch
Talc
Magnesium stearate
Paraffin, light liquid
Xylitab 100 (xylitol (min. 95%), polydextrose)
Cooling flavour (diethyl malonate, maltodextrin (maize), menthol, menthyl lactate, modified starch E1450 (waxy maize), iso-pulegol)
Mint flavour **(**maltodextrin (maize), menthol, modified starch E1450 (waxy maize))

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 25°C. Store in the original package in order to protect from moisture.

6.5 Nature and contents of container

The tablets are packed into PVC/aluminium blisters which are then placed in cardboard cartons to contain 12, 24 or 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 Ltd
The Atrium
Blackthorn Road
Dublin 18

8 MARKETING AUTHORISATION NUMBER

PA1410/053/004

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 28th January 2011

Date of last renewal: 27th January 2016

10 DATE OF REVISION OF THE TEXT

August 2017