Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Rennie Spearmint 680mg / 80mg Chewable tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Calcium carbonate 680 mg (272mg elemental calcium)

Heavy Magnesium Carbonate 80 mg (20 mg elemental magnesium)

Excipients of know effect: Each chewable tablet also contains 250mg Sucrose and 250mg Glucose.

For the 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 spearmint.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For relief of stomach upsets due to hyperacidity and heartburn.

4.2 Posology and method of administration

Posology
Tablets to be taken orally, sucked or chewed.

Adults Only:

One or two tablets to be sucked or chewed as required, to a maximum of eleven tablets a day and should not be taken continuously for longer than 2 weeks.

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

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

Method of administration
For oral use.

4.3 Contraindications

Rennie Spearmint should not be administered in the following cases:

- Hypersensitivity to any of the ingredients of the product, refer to 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 fourteen days, further medical advice should be sought.

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

As with other antacids, Rennie Spearmint 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 insufficency. 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 insuffiency should not take Rennie Spearmint.

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), 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 Rennie Spearmint separately from other drugs, allowing a 1-2 hours interval.

4.6 Fertility, pregnancy and lactation

Pregnancy
Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity.
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 Spearmint tablets can be used during pregnancy if taken as instructed but prolonged intake of high dosages should be avoided.
The maximum recommended daily dose should not be exceeded and should not be taken for more than 2 weeks (see section 4.2).
In order to prevent calcium overload, pregnant women should avoid concomitant excessive intake of milk and dairy products.
Breast-feeding
Calcium and magnesium are excreted in human milk, but at therapeutic doses of Rennie no effects on the breastfed newborns/infants are anticipated.
Rennie Spearmint tablets can be used during breast-feeding 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 Spearmint has no influence on the ability to drive or use machines.

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, 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 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, 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-Code: Calcium carbonate A02ACA1, magnesium carbonate: A02AA01

Rennie Spearmint 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 dependent on systemic absorption. Acting locally in the stomach and oesophagus, they directly neutralize stomach acid and raise both intragastric and oesophageal pH. They protect the gastric and oesophageal mucosa against acid (by neutralisation) and against pepsin (inactivation by an elevated pH). 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 acid neutralization studies (artificial stomach model) showed that Rennie increases stomach pH from pH 1.5-2 to pH 3 in 40 seconds and is able to reach pH 4 in 1 minute 13 seconds. The maximum level of pH achieved in the model was pH 5.24.

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 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

Preclinical studies on Rennie 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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose
Talc
Povidone
*Spearmint flavour
Magnesium stearate
Saccharin sodium
Glucose monohydrate

*composition of spearmint flavour:
Dry flavour composed of:
- mint oils: *Mentha Spicata* L and *Mentha Piperita* L
- acacia
- colloidal anhydrous silica

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 25ºC. Store in the original package.

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, 48 or 96 tablets.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements.

7 MARKETING AUTHORISATION HOLDER

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A94 H2K7
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8 MARKETING AUTHORISATION NUMBER

PA1410/053/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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Date of last renewal: 27 February 2006

10 DATE OF REVISION OF THE TEXT