Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Rennie 750 mg Medicated Chewing Gum

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each medicated chewing-gum contains 750 mg calcium carbonate (300 mg elemental calcium).

Excipients with known effect:
Isomalt (E 953)
Sorbitol (E 420)

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Medicated chewing-gum
Round shape 16 mm chewing-gum, composed of two layers, a blue layer with speckling and a white layer embossed with "750".

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Symptomatic relief of heartburn and acid related symptoms in adults and children from 12 years old.

4.2 Posology and method of administration

Adults and children from 12 years old:
One or two pieces to be taken as a single dose, as required. The product should be taken in case of heartburn or gastric pain which occur usually after meal or at bed time.
The maximum of 8 pieces per day should not be exceeded and should not be taken continuously for longer than 7 days, unless recommended by a healthcare professional.

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

Children:
The safety and efficacy of the product in children aged below 12 years old have not been established. No data are available.

Pregnant women:
One or two pieces to be taken as a single dose, as required. The product should be taken in case of heartburn or gastric pain which occur usually after meal or at bed time.
The maximum of 5 pieces per day should not be exceeded and should not be taken continuously for longer than 1 week. In order to prevent calcium overload, pregnant women should avoid concomitant intake of calcium supplements and excessive intake milk and dairy products (section 4.6).

Method of administration:
The recommended time for chewing is 15 minutes and the remaining gum should not be swallowed.

If symptoms persist in spite of 7 days of continuous therapy, diagnostic measures are strongly recommended in order to rule out a more serious disease.

4.3 Contraindications

Rennie Gum should not be administered in the following cases:

- Hypersensitivity to any of the ingredients of the product
- Hypercalcemia and/or conditions resulting in hypercalcemia
- Nephrolithiasis due to calculi containing calcium deposits and hypercalciuria
- Severe renal insufficiency
- Hypophosphatemia

4.4 Special warnings and precautions for use

Prolonged use should be avoided. The recommended dose should not be exceeded. If symptoms persist after 7 days of treatment or only partly disappear, further medical advice should be sought.

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

As with other antacids, calcium carbonate may mask a malignancy in the stomach.

During therapy at high doses and/or for prolonged periods, and especially in patients with renal insufficiency or during the concomitant treatment with vitamin D, thiazide diuretics and/or calcium-containing nutrients (such as milk) or medicines, there is a risk of hypercalcemia resulting in kidney damage or milk syndrome subsequent renal damage or milk-alkali syndrome.

One medicated chewing-gum contains approximately 416 mg of isomalt, and 170 mg of sorbitol. Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.

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 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.
- Calcium salts can also impede the absorption of phosphates, fluorides, and iron containing products.
- Thiazide diuretics reduce the urinary excretion of calcium. Due to an increased risk of hypercalcemia, serum calcium should be regularly monitored during concomitant use of thiazide diuretics.
- Vitamin D-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
No increased risks of congenital defects have been observed after the use of calcium carbonate during pregnancy.
Rennie Gum could be used during pregnancy if taken as labeled.

The maximum recommended daily dose (5 gums per day) should not be exceeded and should not be taken for more than 7 days (section 4.2). If symptoms persist or only partly disappear after 7 days, medical advice should be sought.

In order to prevent calcium overload, pregnant women should avoid concomitant excessive intake of milk and dairy products.

Breast-feeding
Calcium carbonate is excreted in human milk, but at therapeutic doses of Rennie Gum no effects on the breastfed newborns/infants are anticipated. This medicine can be used during breastfeeding.

Fertility
There is no known evidence suggestive that at recommended dose Rennie Gum have adverse effects on human fertility.

4.7 Effects on ability to drive and use machines

Rennie Gum has noinfluence on the ability to drive and 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 hypercalcemia and alkalosis.

Gastrointestinal Disorders
Nausea, vomiting, stomach discomfort, constipation and diarrhea may occur.

Musculoskeletal and Connective Tissue Disorders
Muscular weakness may occur.

4.8.1 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 can result in renal insufficiency, 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; ATC code: A02A
ATC-Code: Calcium carbonate A02AC01

The mode of action of calcium carbonate is local, based on the neutralization of gastric acid, and is not dependent on systemic absorption.

Calcium carbonate has a rapid, long-lasting and powerful neutralizing action.

Studies have shown that calcium carbonate antacids have upon-contact (immediate) onset of acid neutralization, with clinically relevant pH change occurring within minutes.

5.2 Pharmacokinetic properties

In the stomach, calcium carbonate reacts with the acid in the gastric juice, forming water and soluble mineral salts.
$CaCO_3 + 2\,HCl \rightarrow CaCl_2 + H_2O + CO_2$
Calcium can be absorbed from these soluble salts. However, the degree of absorption is dependent on the subject and the dose. Less than 10% calcium is absorbed.
The small quantities of calcium absorbed are usually excreted rapidly via the kidneys in healthy individuals. In the case of impaired renal function, plasma concentrations of calcium 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 feces.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, toxicity to reproduction.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Acesulfame potassium (E950)
Isomalt (E953)
Menthol flavour (contains a.o. Acacia)
Copovidone
Sorbitol (E420)
Sucralose (E955)
Magnesium stearate
Brilliant blue FCF Aluminium Lake colourant (E133)
Peppermint Extra flavour (contains a.o. Acacia)
Chewing Gum base (contains a.o. Butylhydroxytoluene, BHT)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Store below 30°C.
Store in the original package in order to protect from moisture.

6.5 Nature and contents of container

PVC/PVdC/Alu blisters each containing 10 pieces supplied in cardboard cartons of 10 and 20 pieces.
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

Any unused product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

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A94 H2K7
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8 MARKETING AUTHORISATION NUMBER

PA1410/089/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of First Authorisation: 22nd July 2022

10 DATE OF REVISION OF THE TEXT

November 2022