SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Rennie Gum 750mg Medicated Chewing Gum

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Calcium Carbonate 750mg (300 mg elemental calcium)

Excipients with known effect:

- Isomalt (E 953) 416mg per gum
- Sorbitol (E 420) 170mg per gum

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Medicated chewing gum (chewing gum).

Round bi-layered chewing gum, composed of a speckled blue layer and a white layer embossed with “750”.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the symptomatic relief of heartburn and acid related symptoms, such as indigestion, hyperacidity, flatulence, upset stomach, dyspepsia, biliousness, overindulgence in food and drink, indigestion during pregnancy, acid indigestion, nervous indigestion.

4.2 Posology and method of administration

Adults and children over 12 years:

One or two pieces of gum to be chewed as a single dose as required, usually after meals and before going to bed but also in between in case of heartburn or gastric pain.

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

A maximum daily dose of 8 g calcium carbonate, corresponding to 10 gums a day, must not be exceeded.

Children:

Not recommended for children under 12 years.

As with all antacids, if symptoms persist despite 14 days of continuous therapy, diagnostic measures are strongly recommended in order to rule out a more serious disease.

4.3 Contraindications

This product should not be administered to patients with:

- Hypersensitivity to any of the ingredients of the product
- Hypercalcaemia and/or conditions resulting in hypercalcaemia
- Nephrolithiasis due to calculi containing calcium deposits
- Severe renal insufficiency
- Hypophosphataemia

4.4 Special warnings and precautions for use

Prolonged use should be avoided.

- The stated dose should not be exceeded. If, after 14 days of treatment, symptoms persist or only partly disappear the patient should consult a doctor. As with other antacids, calcium carbonate may mask a malignancy in the stomach.
- Caution should be exercised in patients with mild to moderate impairment of renal function (see section 4.3 – contraindication in severe renal insufficiency). If this product is used in such patients, plasma calcium and phosphate levels should be regularly monitored.

- Long term uses at high doses can result in undesirable effects such as hypercalcaemia resulting in kidney damage or milk syndrome subsequent renal damage or milk-alkali syndrome, especially in patients with renal insufficiency.
- This product should not be used in patients with hypercalciuria (see also section 4.3). Prolonged use increases the risk of formation of renal calculi.
- This product should not be taken with large amounts of milk or dairy products.
- Due to the sorbitol and isomalt content, patients with rare hereditary fructose intolerance (HFI) should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

Changes in gastric acidity, such as that caused by the ingestion of antacids, can affect the rate and degree to which some concurrently administered medicines are absorbed.

- It has been shown that antacids which contain calcium may form complexes with certain substances e.g. antibiotics (such as tetracyclines and quinolones) and cardiac glycosides (e.g. digoxin), biphosphonates, 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 hypercalcaemia, serum calcium should be regularly monitored during concomitant use of thiazide diuretics.
- Vitamin D containing products

Therefore, it is preferable to take the antacid separately from other drugs, allowing at least 4 hours before or after taking eltrombopag and a 1-2 hour interval for all other drugs.

4.6 Fertility, pregnancy and lactation

Pregnancy

Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity.

No increased risks of congenital defects are anticipated, neither have they been observed after the long-term use of calcium carbonate during pregnancy.

This medicine 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. If symptoms persist or only partly disappear after 2 weeks, medical advice should be sought.

In order to prevent calcium overload, pregnant women should avoid concomitant excessive intake of milk and dairy products 1 litre of milk contains up to 1.2 g elemental calcium).

Breastfeeding

Calcium carbonate is excreted in human milk, but at therapeutic doses of the product 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 the recommended dose this medicine has adverse effects on human fertility.

4.7 Effects on ability to drive and use machines

No effects on ability to drive and use machines have been observed.

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, difficulty in breathing and anaphylaxis.

Metabolism and Nutrition Disorders:

Especially in patients with impaired renal function, prolonged use of high doses can result in 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 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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Especially in patients with impaired renal function, prolonged use of high doses of calcium carbonate can result in renal insufficiency, 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 Classification: Antacids

ATC codes: Calcium carbonate: A02AC01

Rennie Gum contains calcium carbonate as an antacid. The mode of action of calcium carbonate is local, based on the neutralisation of gastric acid, and is not dependent on systemic absorption.

Calcium carbonate has a rapid and powerful neutralising action.

In the stomach, Calcium carbonate reacts with excess acid in the gastric juice to produce soluble mineral salts.

$CaCO3 + 2HCl \rightarrow CaCl2 + H2O + CO2$

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 faeces.

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

A small amount of calcium may be absorbed, but in healthy subjects is usually rapidly excreted by the kidney. The soluble chloride produced by the reaction of calcium with gastric acid reacts, in turn, with intestinal, biliary and pancreatic secretions to form insoluble salts, which are excreted in the faeces.

5.3 Preclinical safety data

Preclinical studies on this medicine are not available. The available preclinical data on calcium 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

Acesulfame potassium (E950)

Isomalt (E953)

Menthol Flavour

Copovidone

Sorbitol (E420)

Sucralose (E955)

Magnesium stearate (vegetable)

Brilliant blue FCF Aluminium Lake colourant (E133)

Peppermint Extra flavour

Chewing Gum base (contains a.o. Butylhydroxytoluene, BHT)

6.2 Incompatibilities

None.

6.3 Shelf life

36 months.

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

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

7 MARKETING AUTHORISATION HOLDER

Bayer plc

400 South Oak Way

Reading

RG2 6AD

8 MARKETING AUTHORISATION NUMBER(S)

PL 00010/0755

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

15/04/2025

10 DATE OF REVISION OF THE TEXT

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