SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Rennie Extra Tablets

Rennie Dual Action Chewable Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each chewable tablet contains:
Alginic acid 150mg, calcium carbonate 625mg and heavy magnesium carbonate 73.50mg.
Excipients: each chewable tablet contains 14 mg sodium as well as sucrose (230mg) and glucose (555.22 mg).

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Chewable tablet (tablet)

Off white, speckled circular tablet, flat on both sides with a bevelled edge.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Symptomatic treatment of complaints resulting from gastro-oesophageal reflux and hyperacidity, such as regurgitation and heartburn.

4.2 Posology and method of administration

The usual dose is 2 tablets to be chewed. It should preferably be taken one hour after meals and before going to bed. An additional dose can also be taken in between in the case of heartburn. The maximum dose of 8 grams calcium carbonate (corresponding to 12 tablets) per day should not be exceeded and should not be taken continuously for longer than 2 weeks. Only for use by adults and children over 12 years of age.

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.

For Special warning and precautions for use please also see section 4.4.

4.3 Contraindications

- Severe renal insufficiency
- hypercalcaemia and/or conditions resulting in hypercalcaemia
- pre-existing hypophosphataemia
- nephrolithiasis due to calculi containing calcium deposits
- hypersensitivity to the active substances or to any of the excipients.

4.4 Special warnings and precautions for use

Prolonged use should be avoided.
If the symptoms persist or only partly disappear, further medical advice should be sought.

As with other antacids, Rennie Extra tablets may mask a malignancy in the stomach.

Rennie Extra tablets should not be used in the following cases:
- Hypercalciuria
- In general, caution should be exercised in patients with impaired renal function.
- If Rennie Extra tablets are used in such patients, plasma concentrations of calcium, phosphate and magnesium should be monitored regularly.

In general calcium containing antacids should be carefully administered in patients with constipation, haemorrhoids and sarcoidosis.

Prolonged use of high doses may result in undesirable side-effects such as hypercalcaemia, magnesaemia and the milk alkali syndrome, particularly in patients suffering from renal insufficiency. The product should not be taken with large amounts of milk or dairy products.

Prolonged use increases the risk of formation of renal calculi.

In the literature a possible relationship between calcium carbonate and appendicitis, gastrointestinal haemorrhage, intestinal blockage, or oedema has been reported in single cases.

This medicinal product contains 14 mg sodium per tablet, equivalent to 0.7% of the WHO recommended maximum daily intake of 2g sodium for an adult. This product also contains 230 mg sucrose and about 555.22 mg glucose (including from dextrates) per tablet, which should be taken into account in patients with diabetes.

Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

If symptoms persist after fourteen days, the clinical situation should be reviewed by a healthcare professional.

4.5 Interaction with other medicinal products and other forms of interaction

Changes in the level of acidity of gastric juice such as those caused by taking antacids may affect the degree and speed of absorption of medicines administered concomitantly. It has been shown that antacids containing calcium and magnesium can hinder the absorption of some antibiotics (such as the tetracyclines and quinolones); cardiac glycosides (e.g. digoxin, digitoxin); bisphosphonates; dolutegravir, levothyroxine and eltrombopag.
Calcium salts reduce the absorption of fluoride and iron containing products, and calcium salts and magnesium salts can hinder the absorption of phosphates.
Thiazide diuretics reduce the urinary excretion of calcium. Due to increased risk of hypercalcaemia, serum calcium should be regularly monitored during concomitant use of thiazide diuretics.
In view of possible changes in the rate of absorption of medicines taken concomitantly, it is recommended that antacids are not administered at the same time as other medicines but taken 1 to 2 hours later.

Effects on laboratory parameters:
The administration of antacids may interfere with physiologic values/analytics: urinary system pH may increase while serum concentration of phosphates and potassium may decrease with excessive and prolonged use.

4.6 Fertility, pregnancy and lactation

4.6.1 Pregnancy

No increased risk of congenital defects has been observed after the use of calcium carbonate, magnesium carbonate and alginic acid during pregnancy.

Rennie Extra tablets can be used during pregnancy if taken as labelled.

Pregnant women should limit the length of time the maximum dose is used, which should not be taken for more than 2 weeks (section 4.2).

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

In case of high doses, prolonged intake or renal insufficiency, the risk of hypercalcaemia and/or hypermagnaesia cannot be completely excluded.

4.6.2 Lactation

Calcium and magnesium are excreted into breast milk.

The product is generally considered safe during lactation when used at recommended doses.

4.6.3 Fertility

There is no known evidence suggestive that at recommended dose Rennie Dual Action tablets have adverse effects on human fertility.

4.7 Effects on ability to drive and use machines

Rennie Extra tablets are not expected to affect these functions.

4.8 Undesirable effects

Immune System Disorders:
Hypersensitivity reactions have very rarely been reported. Clinical symptoms may include rash, pruritus, urticaria, angioedema dyspnea and anaphylaxis.

Metabolism and nutrition disorders:
Prolonged use of high doses may possibly result in hypermagnesaemia or hypercalcaemia and alkalosis (GI symptoms such as nausea and vomiting, fatigue, confusion, polyuria, polydypsia, dehydration), particularly in patients with impaired renal function. Prolonged use of high doses of calcium carbonate with milk may lead to Burnett syndrome (milkalkali syndrome).

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 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 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) other measures of rehydration (e.g. infusions) might be necessary.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antacids, other combinations,
ATC code: AO2 AX

Rennie Extra tablets are a combination of two antacids (calcium carbonate and magnesium carbonate) and an alginic acid.

The mode of action of Rennie Extra tablets is local 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.
In healthy volunteers, a significant increase in the pH of stomach contents was achieved within 2 minutes. The total neutralising capacity of two tablets of the product is 29 mEq/H^+(titration to end-point pH 2.5). Apart from the neutralising action of the antacids, the alginic acid present in Rennie Extra tablets cause a viscous gel to be formed which floats on the stomach contents and acts as a physical barrier against reflux.

5.2 Pharmacokinetic properties

Calcium and magnesium
In the stomach: calcium carbonate and magnesium carbonate react with the acid in the gastric juice, forming water and soluble mineral salts.
Calcium and magnesium can be absorbed from these (soluble) salts.

However, the degree of absorption is dependent on the patient and the dose. Approx. 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, serum 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.

Alginic acid
After oral ingestion, alginic acid is not converted in the gastro-intestinal tract; 80-100% of the quantity ingested is excreted. Absorption of alginic salts is negligible.

5.3 Preclinical safety data

Preclinical studies on Rennie Extra Tablets are not available. The available preclinical data on each of the activities 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

Sodium hydrogen carbonate
Sucrose
Glucose monohydrate
Povidone
Talc
Magnesium stearate
Dextrates
Lemon cream flavour (primarily composed of lemon oil, lime oil, orange oil, l-menthole, vanilline, maltodextrin, gum arabic, ascorbic acid, butylhydroxyanisol)
Peppermint flavour (primarily composed of peppermint oil, maltodextrin, gum arabic, silicon dioxide)
Saccharin sodium.

6.2 Incompatibilities

Not applicable.

6.3. Shelf life

3 years

6.4 Special precautions for storage

Do not store above 30°C. Store in the original package in order to protect from moisture.

6.5 Nature and contents of container

Strips consisting of LDPE/Aluminium foil.

Pack-sizes 12, 18, 24, 30, 36 & 48 tablets.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.
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 00010/0514

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30/01/2007 / 29/01/2012

10 DATE OF REVISION OF THE TEXT

04/08/2020