SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Rennie Soft Chews 800mg chewable tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Calcium Carbonate	800.0 mg

Also contains sucrose and glucose
For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Chewable Tablets.
Square green soft chewable tablets

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

For the relief of indigestion, heartburn, nervous indigestion, hyperacidity, flatulence, upset stomach, dyspepsia, biliousness, overindulgence in food and drink, indigestion during pregnancy.

4.2 Posology and method of administration

Posology:
Tablets to be taken orally, sucked or chewed.

Adults and children over 12 years:
One or two tablets to be sucked or chewed as a single dose, preferably to be taken one hour after meals and before going to bed but also in between in case of heartburn or gastric pain. A maximum daily dose of 8 g calcium carbonate corresponding to 10 tablets a day must not be exceeded.

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

Children under 12 years: Not recommended.

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

Rennie should not be administered to patients with:

- Nephrocalcinosis
- Severe renal function impairment (creatinine clearance below 30 ml/min)
- Hypophosphatemia
- Hypersensitivity to the active ingredients or any of the excipients, refer to section 6.1.
- Hypercalcaemia

4.4 Special warnings and precautions for use

- Prolonged use should be avoided.
- Do not exceed the stated dose and if symptoms persist consult your doctor.
- Caution should generally be exercised in the case of patients with impaired renal function. If Rennie 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 and milk-alkali syndrome, especially in patients with renal insufficiency. Prolonged use possibly enhances the risk for the development of renal calculi.
- Calcium carbonate should be used with caution in patients with hypercalciuria
- Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

  Diabetic patients should note that the product contains 1724 mg sucrose. It also contains glucose syrup which contains the equivalent of not more than 1829 mg glucose per tablet.

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 eg., antibiotics (such as tetracyclines and quinolones) and cardiac glycosides, e.g. digoxin, resulting in decreased absorption. This should be borne in mind when concomitant administration is considered.

- Thiazide diuretics reduce the urinary excretion of calcium and increase the serum calcium. Due to an increased risk of hypercalcaemia, serum calcium should be regularly monitored during concomitant use of thiazide diuretics.

- Calcium salts can also impede the absorption of phosphates, fluorides and iron containing products.

- Because of possible changes in the rates of absorption of concurrently administered medicines, it is recommended that antacids should not be taken concurrently with these medicines, but 1 to 2 hours later.

4.6 Pregnancy and lactation

To date, no increased risk of congenital defects has been observed after the use of calcium carbonate during pregnancy. Calcium carbonate can be used during pregnancy if taken as instructed but prolonged intake of high dosages should be avoided. In case of high or prolonged doses or renal insufficiency, the risk for hypercalcaemia can not be completely excluded.

Calcium carbonate can be used during lactation if taken as instructed.

During pregnancy and lactation, it has to be taken into account that the tablets provide a substantial amount of calcium in addition to dietary calcium intake. For this reason, pregnant women should strictly limit their use of tablets to the maximum recommended daily dose 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

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 including anaphylaxis have been reported.

Metabolism and Nutrition Disorders:
Especially in patients with impaired renal function, prolonged use of high doses can result in 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.

Skin and Subcutaneous Disorders:
Rash, urticaria, and angioedema in context of hypersensitive reactions.

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.

4.9 Overdose

Especially in patients with impaired renal function, prolonged use of high doses of calcium carbonate can result in hypercalcaemia, renal insufficiency 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 isotonic 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 Code: Calcium carbonate: A02AC01

Calcium carbonate reacts with excess acid in the gastric medium to produce soluble calcium chloride.

$CaCO_3 + 2HCl \rightarrow CaCl_2 + H_2O + CO_2$

Calcium carbonate has a rapid and powerful neutralising action.
In healthy volunteers, a significant increase in the pH of stomach contents above baseline pH was achieved between 1 and 6 minutes after dosing.

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 react, in turn, with intestinal, biliary and pancreatic secretions to form insoluble salts, which are eliminated with the faeces.

5.3 Preclinical safety data

There are no pre-clinical data which are additional to those already stated in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose

Glucose syrup
Water
Hydrogenated refined vegetable oil
Glycerol
Peppermint flavour
Lecithin
Quinoline yellow (E104)
Brilliant blue (E133)
Purified talc

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months, unopened.

3 months opened. Once the outer packaging has been opened the contents should be used within 3 months.

6.4 Special precautions for storage

Do not store above 25^{o}C.

6.5 Nature and contents of container

Individual tablets are wrapped in a laminate consisting of aluminium foil 7mcm (18.9gsm), and siliconised paper (≥41gsm).

Eight individually wrapped tablets are placed in a heat sealable laminate comprising of PET (Polyethylene Terephthalate) (12mcm), Bleached Kraft paper (39 gsm), low density polyethylene (15mcm), aluminium foil 7.5mcm, and surlyn 35mcm.

3, 4, 5, 6, 7, or 8 sticks of 8 tablets may be packed into a polypropylene flow wrap

Pack sizes: 8, 24, 32, 40, 48, 56, and 64 tablets.

6.6 Special precautions for disposal

No special requirements

7 MARKETING AUTHORISATION HOLDER

Bayer plc
400 South Oak Way
Reading
RG2 6AD

8 MARKETING AUTHORISATION NUMBER(S)

PL 00010/0360

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

19/06/2007

10 DATE OF REVISION OF THE TEXT

13/12/2017