Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Rennie Duo Chewable Tablet

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet of 3,486 mg contains the following active substances:
alginic acid 300 mg, calcium carbonate 1,250 mg and heavy magnesium carbonate 147 mg.

For excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Chewable tablet
White tablet with bevelled edges.

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 1 tablet to be chewed. It should preferably be taken one hour after meals and before going to bed. An additional dose of 1 tablet can also be taken in between in the case of heartburn. Do not take more than 8 tablets in any 24-hour period. Only for use by adults (over 12 years of age).

4.3 Contraindications

Severe renal insufficiency, hypercalcaemia and 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 Duo chewable tablet may mask a malignancy in the stomach.
In general, caution should be exercised in patients with impaired renal function.
If Rennie Duo chewable tablet is used in such patients, plasma concentrations of calcium and magnesium should be monitored regularly.
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.
Prolonged use increases the risk of formation of renal calculi.
Patients on a restricted-sodium diet should note that the product contains 27.5 mg sodium per tablet. Diabetic patients should note that the product contains 460 mg sucrose and about 1040 mg glucose per tablet. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency

should not take this medicine.

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). 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.
Calcium salts and magnesium salts can hinder the absorption of phosphates.
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 these medicines but taken 1 to 2 hours later.

4.6 Pregnancy and lactation

Up to now, no increased risk of congenital defects has been observed after the use of calcium carbonate, magnesium carbonate and alginic acid during pregnancy. In case of high or prolonged doses or renal insufficiency, the risk for hypercalcaemia and/or hypermagnesia can not be completely excluded. Rennie Duo can be used during pregnancy if taken as instructed and if prolonged intake of high dosages is avoided. Rennie Duo can be used during lactation if taken as instructed.

4.7 Effects on ability to drive and use machines

Rennie Duo chewable tablet is not expected to affect these functions.

4.8 Undesirable effects

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 (milk-alkali syndrome).
Although magnesium compounds may have a laxative effect, the low magnesium content in Rennie Duo chewable tablet is not expected to result in undesirable effects in view of the recommended dose. Hypersensitivity reactions, including anaphylactic shock and Quincke oedema have been rarely reported.

4.9 Overdose

Prolonged ingestion of high doses of calcium carbonate may result in hypercalcaemia and alkalosis, which may be expressed in the form of digestive symptoms (nausea, vomiting) and abnormal muscular weakness. In such cases, discontinue administration and take an adequate volume of liquid.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC code: AO2 AX.

Rennie Duo chewable tablet is a combination of two antacids (calcium carbonate and magnesium carbonate) and an alginic acid.

The mode of action of Rennie Duo chewable tablet 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 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 Duo chewable tablet causes 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 soluble 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

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium hydrogen carbonate
Sucrose
Glucose monohydrate
Povidone K30
Talc
Magnesium stearate
Dextrate
Saccharin sodium
Lemon cream flavour
(primarily composed of lemon oil, orange oil, isopropyl myristate, maltodextrin, gum arabic)
Peppermint flavour
(primarily composed of peppermint oil, maltodextrin, gum arabic)

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

3 years.

6.4 Special precautions for storage

No special precautions for storage.

6.5 Nature and contents of container

Polypropylene tube of 10 tablets with LDPE cap containing silica gel as desiccant. Packs of 1 and 2 tubes.
Polypropylene tube of 20 tablets with LDPE cap containing silica gel as desiccant. Pack of 1 tube.
Polypropylene tube of 15 tablets with LDPE cap containing silica gel as desiccant. Packs of 1 and 2 tubes.

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

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Bayer plc
Bayer House
Strawberry Hill
Newbury
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RG14 1JA
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8 MARKETING AUTHORISATION NUMBER

PA 21/76/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 15 September 2000

Date of last renewal: 30 November 2004

10 DATE OF REVISION OF THE TEXT

April 2006