PROFESSIONAL INFORMATION

SCHEDULING STATUS S0

PROPRIETARY NAME AND DOSAGE FORM

DIGESTIF RENNIE® TABLETS

COMPOSITION

Each tablet contains:

Active ingredients: Calcium carbonate 680 mg and magnesium carbonate 80 mg.

Inactive ingredients: Lemon flavour, light liquid paraffin, magnesium stearate, maize starch, peppermint flavour[a], potato starch, saccharin sodium (spearmint flavour only), spearmint flavour[b], sucrose (peppermint & spearmint flavour), talc and water.

Contains sugar: sucrose 475 mg

Contains sweetener: saccharin sodium 0,8 mg

a. In peppermint flavoured tablets only.
b. In spearmint flavoured tablets only.

CATEGORY AND CLASS

11.4.1 - Acid Neutraliser

PHARMACOLOGICAL ACTION

Antacid

Pharmacodynamic properties

Digestif Rennie® is a combination of two antacids, calcium carbonate and magnesium carbonate. The mode of action of calcium carbonate & magnesium carbonate is local, based on the neutralisation of gastric acid, and is not dependent on systemic absorption.

PROFESSIONAL INFORMATION

Pharmacokinetic properties

In the stomach, calcium carbonate and magnesium carbonate react with the acid in the gastric juice, forming water and soluble mineral salts.

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

$MgCO_3 + 2HCl \rightarrow MgCl_2 + H_2O + CO_2$

Calcium and magnesium can be absorbed from these soluble salts.

Calcium and magnesium absorbed are usually excreted rapidly via the kidneys in healthy individuals. In the case of impaired renal function, plasma 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.

INDICATIONS

When an antacid is indicated, such as heartburn and heartburn in pregnancy.

CONTRA-INDICATIONS

Digestif Rennie tablets should not be administered in the following cases:

- 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.

WARNINGS AND SPECIAL PRECAUTIONS

Prolonged use should be avoided. Do not exceed the stated dose and if symptoms persist or only partly disappear, further medical advice should be sought.

Long term use at high doses can result in undesirable effects such as hypercalcaemia, hypermagnesaemia and milk-alkali syndrome, especially in patients with renal insufficiency. Digestif Rennie® should not be taken with large amounts of milk or other dairy products. Prolonged use of Digestif Rennie® increases the risk of formation of renal calculi.

May interfere with the absorption of other medicines given concomitantly (See interactions).

Caution should generally be exercised in the case of patients with impaired renal function. If Digestif Rennie® tablets are used in these patients, plasma calcium, phosphate and magnesium levels should be regularly monitored. Digestif Rennie® should not be used in cases of hypercalciuria.

Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take Digestif Rennie® tablets because they contain 475 mg of sucrose per tablet. This should also be considered by diabetic patients.

INTERACTIONS

Changes in gastric acidity, e.g. during treatment with Digestif Rennie®, may impair the rate and degree of absorption of other medicines, if taken concomitantly.

- Calcium and magnesium may form complexes with certain substances, e.g. antibiotics (tetracyclines, quinolones, and cardiac glycosides, e.g. digoxin, levothyroxine and eltrombopag resulting in decreased absorption. This should be borne in mind when concomitant administration is considered.
- Calcium salts reduce the absorption of fluorides and iron-containing products, and calcium salts and magnesium salts can hinder the absorption of phosphates.
- Therefore, it is preferable to administer Digestif Rennie® separately from other medicines, allowing a 1-2 hours' interval.
- 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.
- Calcium salts may enhance the cardiac effects of digitalis glycosides.

HUMAN REPRODUCTION

No increased risk of congenital defects has been observed after the use of Digestif Rennie® tablets by pregnant women. Digestif Rennie® tablets can be used during pregnancy and lactation if taken as instructed, but prolonged intake of high dosages should be avoided. Pregnant women should limit the use of Digestif Rennie® to the maximum recommended daily doses.

PROFESSIONAL INFORMATION

Clinical experience with Digestif Rennie® has revealed no cases of associated foetal malformations. At the recommended dosage, the use of Digestif Rennie® poses no risk in pregnant or lactating (nursing) women.

There are no controlled studies in pregnancy and lactation; however, Digestif Rennie® is expected to be safe**.**

DOSAGE AND DIRECTIONS FOR USE

Adults and children ≥ 12 years:

1-2 chewable tablets as a single dose, preferably to be taken one hour after meals and before going to bed but also between meals in case of heartburn or epigastric pain. A maximum daily dose of 8 g calcium carbonate (corresponding to 11 Digestif Rennie® tablets) must not be exceeded.

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

Not recommended for children under 12 years of age.

Method of administration:

For oral use. The tablets are to be chewed or sucked. No water is required.

SIDE EFFECTS

- Immune System Disorders:

  Hypersensitivity reactions have been reported. Clinical symptoms may include rash, urticaria, angioedema and anaphylaxis.

- Metabolism and Nutrition Disorders:

  Especially in patients with impaired renal function, prolonged use of high doses can result in hypermagnesaemia or hypercalcaemia and alkalosis which may give rise to gastric symptoms and muscular weakness (see below).

  Milk-alkali syndrome.

PROFESSIONAL INFORMATION

- Gastrointestinal Disorders:

  Nausea, vomiting, stomach discomfort and diarrhoea or constipation may occur.

- Musculoskeletal and Connective Tissue Disorders:

  Muscular weakness may occur.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

Especially in patients with impaired renal function, prolonged use of high doses of Digestif Rennie® can result in renal insufficiency, hypermagnesaemia, hypercalcaemia and alkalosis which may give rise to gastrointestinal symptoms (nausea, vomiting, and 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.

IDENTIFICATION

Cream White Square shaped tablets with rounded corners and concave surfaces engraved "RENNIE", with a smell and taste of either peppermint (peppermint flavour) or spearmint (spearmint flavour).

PRESENTATION

Available in blister packs of 2, 6, 24, 48 and 96 tablets or Roll Wraps of 12 tablets. Available in Peppermint or Spearmint flavours.

STORAGE INSTRUCTIONS

Store in a cool, dry place, at or below 25 °C.

Keep out of the reach of children.

REGISTRATION NUMBER

E/11.4.1/533.

PROFESSIONAL INFORMATION

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

Bayer (Pty) Ltd

27 Wrench Road

Isando

1600

South Africa

Co. Reg. No. 1968/011192/07

DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION

The date on the registration certificate of the medicine: 07 July 1983

The date of the most recently revised professional information as approved by Council: 22 April 2016

NAMIBIA NS0 16/11.4.1/0060 (Peppermint Flavour)
NAMIBIA NS0 16/11.4.1/0061 (Spearmint Flavour)
ZIMBABWE HR E94/16.1/2875 (Peppermint Flavour)
ZIMBABWE HR E95/16.1/2896 (Spearmint Flavour)

Manufactured and packed by Delpharm Gaillard under licence by Bayer AG.