PROFESSIONAL INFORMATION

SCHEDULING STATUS: **S0**

PROPRIETARY NAME AND DOSAGE FORM
RENNIE® DUO, ORAL SUSPENSION

COMPOSITION
Each 10 ml contains:
As Active ingredients:

Calcium carbonate	1 200 mg
Magnesium carbonate	140 mg
Sodium alginate	300 mg

As Inactive ingredients: Chocolate flavour**,** saccharin sodium, sodium bicarbonate, peppermint oil and xanthan gum**.**
Preservatives: Benzyl alcohol 0.3 % m/v and sodium propyl parahydroxybenzoate 0.15 % m/v.
Contains sweetener as saccharin sodium at 10 mg / 10 ml of the suspension.
Sugar free.

CATEGORY AND CLASS
11.4.3 – Antacids, other

PHARMACOLOGICAL ACTION
Antacid and anti-reflux agent

Pharmacodynamics:
RENNIE® DUO contains two antacids; calcium carbonate and magnesium carbonate, and an alginate. The antacids act locally.
Sodium alginate causes a viscous gel (or raft) to form.
Pharmacokinetics:
Calcium carbonate and magnesium carbonate react with acid in gastric juice forming soluble salts.

$CaCO_3 + 2HCl \longrightarrow CaCl_2 + H_2O + CO_2$
$MgCO_3 + 2HCl \longrightarrow MgCl_2 + H_2O + CO_2$

Calcium and magnesium can be absorbed from these (soluble) salts. The degree of absorption is, however patient-dependent and dose-dependent. About 15 % of the calcium and 15-20 % of the magnesium is absorbed.
In healthy individuals, the small quantities of calcium and magnesium absorbed are usually rapidly excreted via the kidneys. Patients with impaired renal function, however, may develop elevated serum concentration of calcium and magnesium.
In the intestinal tract, various non-gastric digestive juices convert the soluble salts into insoluble salts, which are then eliminated in the faeces.
Sodium alginate: Sodium alginate reacts with gastric acid to form a raft (viscous gel). This raft floats on top of the gastric contents. This raft then acts as a mechanical barrier to reduce reflux.
After being taken orally, sodium alginate is not converted in the gastrointestinal tract; 80 – 100 % of the ingested quantity is eliminated. The elimination of alginate salts is negligible.

INDICATIONS
Symptomatic treatment of gastro-oesophageal reflux and hyperacidity.

CONTRAINDICATIONS

RENNIE® DUO should not be administered in the following cases:

- Hypersensitivity to any of the ingredients contained in RENNIE® DUO
- Hypercalcaemia, and/or conditions resulting in hypercalcemia
- Nephrolithiasis due to calculi containing calcium deposits
- Severe renal insufficiency
- Hypermagnesaemia
- Hypophosphatemia (See warnings and special precautions)

WARNINGS and SPECIAL PRECAUTIONS

- Avoid prolonged use.
- Consult a medical practitioner if symptoms persist after 2 weeks of continuous use.
- Do not continue usage for longer than 2 weeks except on the advice of a doctor. Do not give to children under twelve years, except on the advice of a doctor. May interfere with other medicines given concomitantly. **In cases of renal impairment the product should only be used on medical advice.**
- *Renal:* RENNIE® DUO should be used with caution when a state of debility, renal insufficiency or a pre-disposition to kidney stones exists.
- Enough calcium may be absorbed to cause systemic and kidney effects in certain cases. Some of the magnesium may be absorbed and it is usually excreted rapidly in the urine. If kidney function is impaired, hypermagnesaemia may result.
- Effects on ability to drive and use machines
  - There are no studies done on the effects on ability to drive and use machinery.
- RENNIE® DUO contains benzyl alcohol which is associated with serious toxicity in infants.

INTERACTIONS

Changes in gastric acidity, e.g. during treatment with antacids, may impair the rate and degree of absorption of other drugs, if taken.

- It has been shown that antacids containing calcium and magnesium may form complexes with certain substances, e.g. antibiotics (tetracyclines, 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 reduce the absorption of fluorides and iron containing medicines. Calcium salts and magnesium salts can hinder the absorption of phosphates.
- Thiazide diuretics reduce the urinary excretion of calcium. Due to an increased risk of hypercalcemia, serum calcium should be regularly monitored during concomitant use of thiazide diuretics.

Therefore, it is preferable to administer the antacid separately from other medicines, allowing a 1 – 2 hours interval.

HUMAN REPRODUCTION

When taken as directed, RENNIE® DUO may be used during pregnancy and breastfeeding upon consultation of the healthcare professional without risk to the foetus or the infant.

Pregnancy:

- No increased risk of congenital defects has been observed after the use of RENNIE® DUO during pregnancy.
- 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 hypercalcemia and/or hypermagnesaemia cannot be completely excluded.

Lactation:

- Calcium and magnesium are excreted into breast milk.
- RENNIE® DUO is generally considered safe during lactation when used at the recommended doses.

DOSAGE AND DIRECTIONS FOR USE

Route of administration:

For oral use.

Adults and children over 12 years of age:

- The usual single dose is 10 ml suspension. It should preferably be taken one hour after meals and at bedtime.
- An additional dose of 10 ml can also be taken in between in case of heartburn.
- The maximum dose of 8 grams calcium carbonate (corresponding to 60 ml suspension) per day should not be exceeded and should not be taken continuously for longer than 2 weeks.
- As with all antacids, 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.

SIDE EFFECTS

The listed adverse drug reactions are based on spontaneous reports, thus an organization 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, dyspnoea and anaphylaxis.

Metabolism and nutritional disorders:

Especially in patients with impaired renal function, prolonged use of high doses can result in hypermagnesaemia or hypercalcemia and alkalosis.

Gastrointestinal disorders:

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

Musculoskeletal, connective tissue and bone disorders:

Muscular weakness may occur.

Side effects only occurring in the context of milk-alkali syndrome:

Nervous system disorder:

Headache may occur in the context of milk-alkali syndrome.

Renal and Urinary disorders:

Azotemia may occur in the context of milk-alkali syndrome.

Gastrointestinal disorders:

Ageusia may occur in the context of milk-alkali syndrome.

General disorders and administrative site conditions:

Calcinosis and asthenia may occur in the context of milk-alkali syndrome.

KNOWN SYMPTOMS OF OVER-DOSAGE AND PARTICULARS OF ITS TREATMENTS

Especially in patients with impaired renal function, prolonged use of high doses of calcium carbonate and magnesium carbonate can result in renal insufficiency, hypermagnesaemia, hypercalcemia and alkalosis which may give rise to gastrointestinal symptoms (nausea, vomiting, and constipation) and muscular weakness. In these cases, the intake of RENNIE® DUO 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.

IN THE EVENT OF OVERDOSAGE, CONSULT YOUR DOCTOR OR PHARMACIST. IF NEITHER IS AVAILABLE, SEEK HELP AT CONTACT THE NEAREST HOSPITAL OR POISON CONTROL CENTRE.

IDENTIFICATION
Cream to light brown homogenous suspension with a mint and chocolate aroma.

PRESENTATION
100 ml, 150 ml and 250 ml transparent amber glass bottles with white opaque HDPE screw caps with tamper-evident safety rings and inner LDPE stoppers, containing not less than 100 ml, 150 ml and 250 ml suspension. The bottles are packed into folding cartons.

STORAGE INSTRUCTIONS
Store at or below 25 °C, in a cool dry place. Keep the bottle tightly closed.
KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER
41/11.4.3/0449

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION
Bayer (Pty) Ltd
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