PROFESSIONAL INFORMATION

SCHEDULING STATUS

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PROPRIETARY NAME AND DOSAGE FORM

DIGESTIF RENNIE® ORANGE TABLET

COMPOSITION

Active ingredients:	Calcium Carbonate	680 mg
	Magnesium Carbonate Heavy	80 mg
Inactive ingredients:	Light liquid paraffin, magnesium stearate, orange flavour, potato starch, pre-gelatinised maize starch, saccharin sodium, sucrose and talc.	

"Contains sugar" as sucrose at 475 mg/ tablet

CATEGORY AND CLASS

11.4.1 - Acid Neutraliser

PHARMACOLOGICAL ACTION

Pharmacodynamics properties

Antacids react with hydrochloric acid to form chlorides, water and carbon dioxide and neutralizing the hydrochloric acid. Calcium carbonate neutralizes hydrochloric acid rapidly and effectively. Magnesium carbonate reacts more slowly owing to its crystal structure.

Pharmacokinetic properties

Antacids are cleared from the empty stomach in about 30 minutes. The presence of food alone elevates gastric pH to about 5 for approximately 1 hour and prolongs the neutralizing effects of antacids for about 2 hours. Magnesium salts increase intestinal motility. Unreacted insoluble antacids pass through the intestines and are eliminated in the faeces. Magnesium carbonate administered by mouth, reacts with gastric acid to form soluble magnesium chloride and carbon dioxide in the stomach. Some magnesium is slowly absorbed from the gastro intestinal tract and

eliminated in the urine; otherwise excretion is via the faeces. Calcium carbonate is converted to calcium chloride by gastric acid. Some of the calcium is absorbed from the intestine but about 85 % is reconverted to insoluble calcium salts, such as carbonate and is excreted in the faeces.

INDICATIONS

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

CONTRA-INDICATIONS

Hypermagnesaemia, hypercalcaemia or alkalosis.

Hypersensitivity to any of the ingredients.

WARNINGS and SPECIAL PRECAUTIONS

Do not continue usage for longer than 2 weeks except on the advice of a doctor. Do not give to children under five years, except on the advice of a doctor. May interfere with the absorption of other medicines given concomitantly (See "INTERACTIONS"). In cases of renal impairment the product should only be used on medical advice.

Renal: **DIGESTIF RENNIE® ORANGE TABLET** 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 renal effects in certain cases. Some of the magnesium may be absorbed and it is usually excreted rapidly in the urine. If renal function is impaired, hypermagnesaemia may result.

INTERACTIONS

DIGESTIF RENNIE® ORANGE TABLET may interfere with the absorption of other medicines, e.g. iron, tetracyclines and vitamins, if taken concomitantly. Calcium salts may enhance the cardiac effects of digitalis glycosides.

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HUMAN REPRODUCTION

Clinical experience with **DIGESTIF RENNIE® ORANGE TABLET** has revealed no cases of associated foetal malformations. At the recommended dosage, the use of **DIGESTIF RENNIE® ORANGE TABLET** poses no risk in pregnant or lactating (breast feeding) women.

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.

SIDE EFFECTS

Gastro-intestinal:

Very rare (<1/10,000)

Calcium carbonate may cause constipation. However, the magnesium carbonate may counteract the latter tendency since magnesium salts are known to be mildly laxative in action.

Flatulence from released carbon dioxide is usually not serious. Eructations may occur in some patients.

Metabolic:

Very rare (<1/10,000)

Alkalosis, hypercalcaemia, acid rebound and milk-alkali syndrome has occurred usually in patients taking doses higher than the recommended dosage or in patients with renal impairment.

PROFESSIONAL INFORMATION

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

Hypercalcaemia and alkalosis which may occur with excessive doses of calcium carbonate respond to withdrawal of tablets. If renal function is impaired, hypermagnesaemia may result which is rapidly reversed by calcium salts given intravenously.

IN THE EVENT OF OVERDOSAGE CONTACT A MEDICAL DOCTOR OR THE NEAREST HOSPITAL.

IDENTIFICATION

Cream white square shaped tablets with rounded corners and concave surfaces engraved "RENNIE", with a smell and taste of orange (orange flavour)

PRESENTATION

Available in blister packs of 24 and 48 tablets. The blister pack is made up of transparent, rigid polyvinyl chloride (PVC) with aluminium foil backing. The blister pack has Rennie®, the BAYER logo with the batch number and expiry date printed on.

STORAGE INSTRUCTIONS

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

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

41/11.4.1/0772

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

PROFESSIONAL INFORMATION

DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION

Date on the registration certificate: 09 October 2009

Date of the most recently revised professional information: 09 October 2009

NAMIBIA NS0 16/11.4.1/0059

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