Applicant: Bayer (Pty) Ltd
Product Proprietary Name: Digestif Rennie® Orange
Dosage Form: Compressed tablets
Strength: Calcium Carbonate 680 mg; Magnesium Carbonate 80 mg

PATIENT INFORMATION LEAFLET **DATE 27 FEBRUARY 2015**

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S0

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

DIGESTIF RENNIE® ORANGE TABLET

Read all of this leaflet carefully because it contains important information for you

DIGESTIF RENNIE® ORANGE TABLET is available without a doctor's prescription, for heartburn and heartburn in pregnancy. Nevertheless you still need to use DIGESTIF RENNIE® TABLETS carefully to get the best results.

- Keep this leaflet. You may need to read it again.
- Do not share DIGESTIF RENNIE® ORANGE TABLET with any other person
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 2 weeks.

WHAT DIGESTIF RENNIE® ORANGE TABLET CONTAINS

Active ingredient is: Calcium carbonate 680 mg,
Magnesium carbonate 80 mg

The other ingredients are: Light liquid paraffin, magnesium stearate, orange flavour, potato starch, pre-gelatinised maize starch, saccharin sodium sucrose and talc.

WHAT DIGESTIF RENNIE® ORANGE TABLET IS USED FOR

Antacid

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

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BEFORE YOU TAKE DIGESTIF RENNIE® ORANGE TABLET

In cases of renal impairment the product should only be used on medical advice.

DIGESTIF RENNIE® ORANGE TABLET should be used with caution when a state of debility, renal insufficiency or a pre-disposition to kidney stones exists.

Do not take DIGESTIF RENNIE® ORANGE TABLET if:

- If you suffer from hypermagnesaemia, hypercalcaemia or alkalosis
- If you are hypersensitive to any of the ingredients.

Take special care with DIGESTIF RENNIE® ORANGE TABLET:

- If you have renal damage
- Do not give to Children under 5 years of age
- Do not use for more than two weeks except on the advice of a medical practitioner.

Pregnancy and Breastfeeding

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.

If you are pregnant or breastfeeding your baby please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

There are no controlled studies in pregnancy and lactation; however **DIGESTIF RENNIE® ORANGE TABLET** is expected to be safe**.**

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HOW TO TAKE DIGESTIF RENNIE® ORANGE TABLET

You should check with your doctor or a pharmacist if you are unsure. The usual dose is:

Adults:

One or two tablets to be sucked or chewed half hourly as required. Not more than twelve tablets to be taken in 24 hours.

Children 5 - 8 years:

Half to one tablet half hourly as required. Not more than four tablets to be taken in 24 hours.

Children 9 - 12 years:

One to two tablets half hourly as required. Not more than eight tablets to be taken in 24 hours.

If you take more DIGESTIF RENNIE® ORANGE TABLET than you should:

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, CONSULT YOUR DOCTOR OR PHARMACIST. IF NEITHER IS AVAILABLE, CONTACT THE NEAREST HOSPITAL OR POISON CONTROL CENTRE.

POSSIBLE SIDE EFFECTS

DIGESTIF RENNIE® ORANGE TABLET can have side effects.

- Calcium carbonate may cause constipation. However, the magnesium carbonate may affect 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.

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- 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.

'Not all side-effects reported for DIGESTIF RENNIE® ORANGE TABLETS are included in this leaflet. Should your general state of health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor pharmacist or other healthcare professional for advice.'

STORING AND DISPOSING OF DIGESTIF RENNIE® ORANGE TABLET

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

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

Do not use after the expiry date on the carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets)

PRESENTATION OF DIGESTIF RENNIE® ORANGE TABLET

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 no. and expiry date printed on.

IDENTIFICATION OF DIGESTIF RENNIE® ORANGE TABLET

DIGESTIF RENNIE® ORANGE TABLET is presented as Cream white square shaped tablets with rounded corners and concave surfaces engraved "RENNIE", with a smell and taste of orange (orange flavour)

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REGISTRATION NUMBER

41/11.4.1/0772

NAME AND ADDRESS OF THE REGISTRATION HOLDER

Bayer (Pty) Ltd

27 Wrench Road

Isando

1600

South Africa

Co. Reg. No.1968/011192/07

DATE OF PUBLICATION OF THIS PATIENT INFORMATION LEAFLET

Date on the registration certificate: 09 October 2009

Date of the most recently revised package insert: 09 October 2009

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