SCHEDULING STATUS: S0

DIGESTIF RENNIE® TABLETS

Calcium carbonate 680 mg and magnesium carbonate 80 mg

Contains sugar: sucrose 475 mg/tablet; (**peppermint flavoured)**

Contains sweetener: saccharin sodium 0,8 mg/tablet **(spearmint flavoured**)

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

Digestif RENNIE® is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to take Digestif RENNIE® Tablets carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share Digestif RENNIE® 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 14 days of treatment.

What is in this leaflet

1. What Digestif RENNIE® is and what it is used for
2. What you need to know before you take Digestif RENNIE®
3. How to take Digestif RENNIE®
4. Possible side effects
5. How to store Digestif RENNIE®
6. Contents of the pack and other information

1. What Digestif RENNIE® is and what it is used for

Digestif RENNIE® is a combination of two antacids, calcium carbonate and magnesium carbonate. Digestif RENNIE® tablets are used for the symptomatic relief of acid-related symptoms, e.g. heartburn and heartburn in pregnancy.

2. What you need to know before you take Digestif RENNIE®

Do not take Digestif RENNIE® Tablets:

If you are allergic to any of the ingredients; If your calcium blood levels are high; If you have kidney stones;

If your kidneys are not functioning normally; If your phosphorus blood levels are low.

Warnings and precautions

Take special care with Digestif RENNIE® Tablets:

Avoid prolonged use • Do not exceed the recommended dose • If the symptoms do not disappear after 14 days of continuous treatment, consult your doctor • Diabetics should take special care with Digestif RENNIE® as it contains 475 mg sugar per tablet • If you have hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency • Do not take Digestif RENNIE® tablets if you have high calcium levels in your urine • Allow a 1 – 2 hours interval between taking Digestif RENNIE® tablets and antibiotics (tetracyclines, quinolones); cardiac glycosides (digoxin) or levothyroxine and eltrombopag • Do not give Digestif RENNIE® to children under 12 years of age • Do not take Digestif RENNIE® tablets for more than one week. Avoid concomitant, excessive intake of milk and dairy products to prevent calcium overload.

Other medicines and Digestif RENNIE® Tablets

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

Treatment with Digestif RENNIE® tablets may affect the rate and the extent of absorption of other medicines, if taken at the same time. The affected medicines include antibiotics (tetracyclines, quinolones); cardiac glycosides (digoxin) or levothyroxine and eltrombopag**.** Allow a 1 – 2 hours' interval between taking your other medicines and Digestif RENNIE® tablets

Do not take Digestif RENNIE® tablets if you have high calcium levels in your urine

Digestif RENNIE® Tablets with food, drink and alcohol

.Avoid concomitant, excessive intake of milk and dairy products to prevent calcium overload.

Pregnancy and Breastfeeding:

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

If you are pregnant, do not take Digestif RENNIE® tablets in the first three months of pregnancy without consulting your doctor. Do not exceed the recommended daily dose.

Driving and using machinery:

Digestif RENNIE® tablets are not expected to affect these functions.

Digestif RENNIE® tablets contains sucrose

Diabetics should take special care with Digestif RENNIE® as it contains 475 mg sugar per tablet • If you have hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency •

3. How to take Digestif RENNIE® tablets

Do not share Digestif RENNIE® with any other person.

The tablets are to be chewed or sucked. No water is required.
Chew 1 to 2 tablets one hour after meals and before going to bed but also in between in case of heartburn or gastric pain. Do not take more than 11 tablets in a day. You must inform your doctor if there is no improvement after 14 days of continuous treatment.

If you take more Digestif RENNIE® tablets than you should

You may experience the following symptoms: nausea, vomiting, constipation and muscular weakness. In these cases, stop taking the medicine immediately and take lots of fluids. In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

4. Possible side effects:

Digestif RENNIE® tablets can have side effects.

Some of the side effects that you are likely to experience are the following: Nausea, vomiting, stomach discomfort, diarrhoea or constipation. • If you are hypersensitive to any of the ingredients of Digestif RENNIE® tablets you may experience the following symptoms: rash, hives, rapid swelling and difficulty in breathing, severe allergic reaction and muscular weakness. • In the event that your blood calcium levels are raised, you may experience the following symptoms: loss or impairment of sense of taste and headache.

Not all side effects reported for Digestif RENNIE® are included in this leaflet. Should your general health worsen while taking Digestif RENNIE®, please consult your doctor, pharmacist or other health care professional for advice.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8 or or you can report the side effects directly to Bayer Pharmacovigilance Department by sending an email to zapv@bayer.com or via the Bayer website www.bayer.co.za.

By reporting side effects, you can help provide more information on the safety of Digestif RENNIE®.

5. How to store Digestif RENNIE® tablets

Keep all medicines out of the reach and sight of children.
Store at or below 25 °C.
Do not use after the expiry date stated on the blister pack and the carton.
Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets)

6. Contents of the pack and other information

What Digestif RENNIE® contains

The active substances are: Calcium carbonate 680 mg and magnesium carbonate 80 mg

The other ingredients are: Lemon flavour[a], light liquid paraffin, magnesium stearate, maize starch, peppermint flavour[a], potato starch, saccharin sodium[b], spearmint flavour[b], sucrose, talc and water.

Contains sugar: sucrose 475 mg/tablet; **Contains sweetener:** saccharin sodium 0,8 mg/tablet

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

What Digestif RENNIE® looks like and contents of the pack

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).

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

Holder of Certificate of Registration

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Access to the corresponding Professional Information

www.bayer.co.za

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