

BAYER ARTWORK PANEL

Bayer Ref No: **BAY390710**
 Trident Reference No: TR1681874
 Brand: Rennie
 Range: Chew Tablets
 Product: Peppermint
 Pack Type: Leaflet
 Pack Size: 48/96 Pack
 Action: **A**
 Date: 05/12/19
 Country: Namibia/South Africa

Finished Goods Code: **10012634 10012631 10012566 10012570**
 Synaps Request Code: **TLO23004**
 Component Code: **103822 / 0819ZA**

CAD Ref No: PIL 300x135 (SB727)
 Printer: Imprimerie Lefrancq (Cande, France)
 Packaging Site: Delpharm Gaillard France [FR]
 Substrate: White Paper

Barcode 1 Type: Code 128
 Barcode 1 Mag: 44.5%
 Barcode 2 Type: N/A
 Barcode 2 Mag: N/A
 Pharmacode No/NE: N/A

Technical & Non Printing Items
 Cutter Guides

Colours
 Process Black
 1
 LTH



Connaught House, Connaught Road,
 Kingswood Business Park, Hull, HU7 3AP, England.
 T: +44 (0) 1482 828100

Please note that any low resolution paper Canon colour copies associated with this job should be referred to for content, layout and colour separation only.

UNDER NO CIRCUMSTANCES SHOULD THIS ARTWORK BE ALTERED WITHOUT PRIOR PERMISSION FROM TRIDENT.

STUDIO USE ONLY **Philip Ives** v1.0
 Sm*Art check results: G=1; O=0; R=0; - P1 - 05/12/19 17:48:52

FONT SIZE PANEL

Main Text (body copy): 7 pt
 Height (based on lower case x): 1.2 mm

ARTWORK APPROVAL PANEL

Packaging Site Approval:
 Name: **Approval of the technical part**
 A. MANIGAND
 Date:
 Action: **Graphic part is under your responsibility.**

Country Approval:
 Name: *Hamzeh Majid*
 Date: 06/01/2020
 Action:



135 mm

PATIENT INFORMATION LEAFLET
 SCHEDULING STATUS: [50]



103822 / 0819ZA

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:
 DIGESTIF RENNIE® TABLETS

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 DIGESTIF RENNIE® TABLETS CONTAINS:

The active substances are: Calcium carbonate 680 mg and magnesium carbonate 80 mg
 The other ingredients are: Lemon flavour¹, light liquid paraffin, magnesium stearate, maize starch, peppermint flavour², potato starch, saccharin sodium³, spearmint flavour², sucrose, talc and water.

¹Contains sugar: sucrose 475 mg/tablet; Contains sweetener: saccharin sodium 0,8 mg/tablet
²a. In peppermint flavoured tablets only. b. In spearmint flavoured tablets only.

WHAT DIGESTIF RENNIE® TABLETS ARE USED FOR:

Digestif Rennie® tablets are used for the symptomatic relief of acid-related symptoms, e.g. heartburn and heartburn in pregnancy.

BEFORE YOU TAKE DIGESTIF RENNIE® TABLETS:

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.

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 sucrose-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.

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.

Taking other medicines with 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

HOW TO TAKE DIGESTIF RENNIE® TABLETS:

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.

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.

STORING AND DISPOSING OF DIGESTIF RENNIE® TABLETS:

Keep all medicines out of the reach and sight of children. Do not store above 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)

PRESENTATION OF DIGESTIF RENNIE® TABLETS: Available in blister packs of 2, 6, 24, 48 and 96 tablets or Roll Wraps of 12 tablets. Available in Peppermint or Spearmint flavours.

IDENTIFICATION OF DIGESTIF RENNIE® TABLETS: 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).

REGISTRATION NUMBER: E/11.4.1/533

NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

Bayer (Pty) Ltd., 27 Wrench Road, Isando, 1600, Co. Reg No. 1968/011192/07, +27 11 921 5000

DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET:

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

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

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

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

The professional information is available online at www.bayer.co.za

Bayer

PASIENT SEINLIGTINGSBLAD
 SKEDULERINGSTATUS: [50]



HANDELSNAAM, STERKTE EN DOSEERVORM:
 DIGESTIF RENNIE® TABLETTE

Lees alles op hierdie blaadjie noukeurig, aangesien dit belangrike inligting vir u bevat

Digestif Rennie® is sonder 'n geneesheer se voorskrif vir u beskikbaar om 'n ligte siekte te behandel. Nietemin, vir die beste resultate behoort u Digestif Rennie® Tablette versigtig te gebruik.

• Hou hierdie blaadjie. U sal dit dalk weer wil lees. • Moenie Digestif Rennie® met enige ander persoon deel nie. • Vra u apteker indien u meer inligting of advies benodig. • U moet 'n geneesheer raadpleeg, indien u simptome verswak of nie na 14 dae van behandeling verbeter nie.

WAT DIGESTIF RENNIE® TABLETTE BEVAT:

Die aktiewe bestanddele is: Kalsiumkarbonaat 680 mg en magnesiumkarbonaat 80 mg

Die ander bestanddele is: Suurleimoengeursel¹, ligte aptekersparaffien, magnesiumstearaat, melietystsel, pepermentgeursel², aartappelstysel, natriumsakkarien³, groenmentgeursel², sukrose, talkum en water.

Bevat suiker: sukrose 475 mg/tablet; Bevat versoeter: natriumsakkarien 0,8 mg/tablet
¹a. Slegs in pepermentgeurde tablette. b. Slegs in groenmentgeurde tablette.

WAARVOOR WORD DIGESTIF RENNIE® TABLETTE GEBRUIK:

Digestif Rennie® tablette word gebruik vir die simptomatiese verligting van suurverwante simptome, bv. sooibrand en sooi-brand tydens swangerskap.

VOORDAT U DIGESTIF RENNIE® TABLETTE NEEM:

Moenie Digestif Rennie® Tablette neem nie:

Indien u vir enige van die bestanddele allergies is; Indien u kalsiumbloedvlakke hoog is; Indien u nierstene het; Indien u niere nie normaal werk nie; Indien u fosforbloedvlakke laag is.

Neem spesiale sorg met Digestif Rennie® Tablette:

Vermy langdurige gebruik • Moenie die aanbevole dosis oorskry nie • Indien die simptome nie na 14 dae van aanhoudende gebruik verdwyn nie, raadpleeg u geneesheer • Diabetikers moet spesiale sorg met Digestif Rennie® neem, aangesien dit 475 mg suiker per tablet bevat • Indien u ooreetlike probleme van fruktose onverdraagbaarheid, glukose-galaktose opnemingsgebrek of sukrase-isomaltase onvoldoendheid het • Moenie Digestif Rennie® tablette neem, indien u hoë kalsiumvlakke in u urine het nie • Laat 'n 1 – 2 uur interval toe tussen die neem van Digestif Rennie® tablette en antibiotika (tetrasiel, kinolone); hartglukosiede (digoksien) of levotiroksien en eltrombopag • Moenie Digestif Rennie® aan kinders jonger as 12 jaar gee nie • Moenie Digestif Rennie® tablette vir meer as een week neem nie. Vermoeg gelyktydig, oormatige inname van melk en suivelprodukte om kalsiumooring te voorkom.

Swangerskap en Borsvoeding:

Indien u swanger is of u baba borsvoed, raadpleeg asseblief u geneesheer, apteker of ander gesondheidsorgdeskundige voordat hierdie medisyne geneem word.

Indien u swanger is, moenie Digestif Rennie® tablette in die eerste drie maande van swangerskap neem, sonder om u geneesheer te raadpleeg nie. Moenie die aanbevole daaglikse dosis oorskry nie.

Bestuur en gebruik van masjiene:

Daar word nie verwag dat Digestif Rennie® tablette 'n effek op hierdie funksies sal hê nie.

Neem van ander medisyne met Digestif Rennie® Tablette:

Laat weet altyd u gesondheidsorgdeskundige, indien u enige ander medisyne neem. (Dit sluit komplementêre of tradisionele medisyne in.)
 Behandeling met Digestif Rennie® tablette kan die tempo en mate van absorpsie van ander medisyne beïnvloed, indien dit terselfdertyd geneem word. Die betrokke medisyne sluit in antibiotika (tetrasiel, kinolone); hartglukosiede (digoksien) of levotiroksien en eltrombopag. Laat 'n 1 – 2 uur interval toe tussen die neem van u ander medisyne en Digestif Rennie® tablette.

HOE OM DIGESTIF RENNIE® TABLETTE TE NEEM:

Die tablette moet gekou of gesuig word. Geen water is nodig nie. Kou 1 tot 2 tablette een uur na maaltye en voor slapenstyd, maar ook tussen maaltye in geval van sooi-brand of epigastriese pyn. Moenie meer as 11 tablette per dag neem nie. U moet u geneesheer inlig, indien daar geen verbetering na 14 dae se aanhoudende behandeling is nie.

Indien u meer Digestif Rennie® tablette geneem het as wat u moes:

U kan die volgende simptome ondervind: naarheid, braking, hardlywigheid en spierswakheid. In hierdie gevalle, staak die medisyne onmiddellik en drink baie vloeistowwe. In die geval van oordosis, raadpleeg u geneesheer of apteker. Indien nie een van hulle beskikbaar is hie, soek hulp by die naaste hospitaal of gifbeheersentrum.

MOONTLIKE NEWE-EFFEKTE:

Digestif Rennie® tablette kan nuwe-effekte hê.

Sommige van die nuwe-effekte wat u moontlik kan ondervind, is die volgende: Naarheid, braking, maagongerief, diaree of hardlywigheid.

• Indien u hipersensitief vir enige van die bestanddele van Digestif Rennie® tablette is, kan u die volgende simptome ondervind: uitslag, netelroos, winnige swelling en moeilike asemhaling, ernstige allergiese reaksie en spierswakheid. • In die geval dat u bloedkalsiumvlakke verhoog is, kan u die volgende simptome ondervind: verlies of belemmering van smaaksintuig en hoofpyn.

Nie al die nuwe-effekte wat vir Digestif Rennie® tablette aangemeld is, is in hierdie blaadjie ingesluit nie. Indien u algemene gesondheidstoestand agteruitgaan, terwyl u Digestif Rennie® neem, raadpleeg asseblief u geneesheer, apteker of ander gesondheidsorgdeskundige.

BERGING EN WEGDOEN VAN DIGESTIF RENNIE® TABLETTE:

Hou alle medisyne buite bereik en sig van kinders. Moenie bo 25 °C bewaar nie. Moenie na die vervaldatum wat op die stolpstroke en die karton gedruk is, gebruik nie. Neem alle ongebruikte medisyne terug na u apteker. Moenie ongebruikte medisyne in afvoerpype of rioolsisteme (bv. toilette) weggooi nie.

AANBIEDING VAN DIGESTIF RENNIE® TABLETTE: Beschikbaar in stolpverpakkings van 2, 6, 24, 48 en 96 tablette of Roll Wraps van 12 tablette. Beschikbaar in Peperment- of Groenmentgeursels.

IDENTIFIKASIE VAN DIGESTIF RENNIE® TABLETTE: Roomkleurige wit vierkantige tablette met ronde kante en konkawe oppervlakte wat met "RENNIE" gegraveer is, met 'n reuk en smaak van peperment (pepermentgeursel) of groenment (groenmentgeursel).

REGISTRASIE-NOMMER: E/11.4.1/533

NAAM, SAKEADRES EN TELEFOONNOMMER VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT:

Bayer (Edms) Bpk, Wrenchweg 27, Isando, 1600, Maatskappy Reg nr. 1968/011192/07, +27 11 921 5000

DATUM VAN PUBLIKASIE VAN DIE PASIENT SE INLIGTINGSBLAD:

Die datum op die medisyne se registrasiesertifikaat: 07 Julie 1983

Die datum van die onlangs hersiene pasiënt se inligtingsblad soos deur die Raad goedgekeur: 22 April 2016

NAMIBIA NS0 16/11.4.1/0060 (Peperment geur)	ZIMBABWE HR E94/16.1/2875 (Peperment geur)
NAMIBIA NS0 16/11.4.1/0061 (Groenment geur)	ZIMBABWE HR E95/16.1/2896 (Groenment geur)

Bayer