RENNIE ICE SUGAR FREE
PL 00010/0624

UKPAR

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RENNIE ICE SUGAR FREE
PL 00010/0624

LAY SUMMARY

The MHRA granted Bayer PLC a Marketing Authorisation (licence) for the medicinal product Rennie Ice Sugar Free on 19th May 2009. This product is a mint flavour antacid tablet which quickly relieves:

- indigestion
- heartburn
- acid indigestion
- dyspepsia
- hyperacidity
- gastritis
- nervous indigestion
- flatulence
- upset stomach
- indigestion during pregnancy
- biliousness
- over indulgence in food and drink

This product, to be available on a general-sales licence (GSL), contains calcium carbonate and magnesium carbonate.

This application is a duplicate of a previously granted application for Rennie Sugar Free (PL 00010/0362), approved originally as Sugar free Rennie (PL 00188/0109) to Nicholas Laboratories Limited on 23rd July 1990 and underwent a change of ownership on 1st of December 2000 to Roche Products Limited (PL 00031/0578), then underwent a second change of ownership on 1st July 2005 to Bayer PLC (PL 00010/0362).

No new or unexpected safety concerns arose from this simple application and it was, therefore, judged that the benefits of taking Rennie Ice Sugar Free outweigh the risks; hence a Marketing Authorisation has been granted.

RENNIE ICE SUGAR FREE
PL 00010/0624

SCIENTIFIC DISCUSSION

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INTRODUCTION

The UK granted Bayer PLC a marketing authorisation for the medicinal product Rennie Ice Sugar Free (PL 00010/0624) on 19th May 2009. The product is available on a General-Sales Licence (GSL).

The application was submitted as a simple abridged application according to Article 10c (formerly Article 10.1(a)(i)) of Directive 2001/83/EC, cross-referring to Rennie Sugar Free (PL 00010/0362), which was originally approved to Bayer PLC on 1st July 2005.

No new data were submitted nor were they necessary for this simple application, as the data are identical to that of the previously granted cross-reference product.

This is a chewable tablet and is indicated for the relief of indigestion, heartburn, nervous indigestion, hyperacidity, flatulence, upset stomach, dyspepsia, biliousness, gastritis, overindulgence in food and drink, indigestion during pregnancy.

PHARMACEUTICAL ASSESSMENT

LICENCE NO: PL 00010/0624
PROPRIETARY NAME: Rennie Ice Sugar Free
ACTIVE(S): Magnesium carbonate and calcium carbonate
COMPANY NAME: Bayer PLC
E.C. ARTICLE: Article 10c (formerly Article 10.1(a)(i)) of Directive 2001/83/EC
LEGAL STATUS: GSL

1. INTRODUCTION

This is a simple, piggy back application for Rennie Ice Sugar Free (PL 00010/0624) submitted under Article 10c (formerly Article 10.1(a)(i)) of Directive 2001/83/EC. The proposed MA holder is Bayer PLC, Bayer House, Strawberry Hill, Newbury, Berkshire, RG14 1JA, United Kingdom.

The application cross-refers Rennie Sugar Free (PL 00010/0362), which was originally approved to Bayer PLC on 1st July 2005.
The current application is considered valid.

2. MARKETING AUTHORISATION APPLICATION FORM

2.1 Name(s)

The proposed name of the product is Rennie Ice Sugar Free. The product has been named in-line with current requirements.

2.2 Strength, pharmaceutical form, route of administration, container and pack sizes

The product's pharmaceutical form is chewable tablets for oral use that contain 80mg heavy magnesium carbonate and 680mg calcium carbonate. The finished product is packed in aluminium foil/polyvinyl chloride (PVC) bubble packs with six or twelve tablets per strip, of which 3, 4, 6 or 8 strips are packed in a cardboard carton. For the 12 tablet pack, the tablets are roll wrapped in laminated foil. Pack sizes are 12, 24, 36, 48, 72 and 96 Tablets.

For the 12 tablet Pocket Pack, the tablets are packed in a hard tempered aluminium foil (20µm)/clear thermoformable PVC (250µm) bubble pack, with six tablets per strip. Two strips are packed in a cardboard pocket pack.

The proposed shelf-life is 36 months for the blister packs with the storage conditions 'Do not store above 25°C.' and 'Protect from moisture.' The proposed shelf-life for the roll wraps is 24 months with the storage conditions 'Protect from moisture.'
These are consistent with the details registered for the cross-reference product.

2.3 Legal status

On approval, the product will be available on a general-sales licence (GSL).

2.4 Marketing authorisation holder/Contact Persons/Company

Bayer PLC, Bayer House, Strawberry Hill, Newbury, Berkshire, RG14 1JA, United Kingdom.

The QP responsible for pharmacovigilance is stated and his CV is included.

2.5 Manufacturers
The proposed manufacturing sites are consistent with those registered for the cross-reference product and evidence of GMP compliance has been provided.

2.6 Qualitative and quantitative composition
The proposed composition is consistent with the details registered for the cross-reference product.

2.7 Manufacturing process
The proposed manufacturing process is consistent with the details registered for the cross-reference product and the maximum batch size for each product is stated.

2.8 Finished product/shelf-life specification
The proposed finished product specification is in-line with the details registered for the cross-reference product.

2.9 Drug substance specification
The proposed drug substance specification is consistent with the details registered for the cross-reference product.

2.10 TSE Compliance
No materials of animal or human origin are included in the product.
This information is consistent with the cross-reference product.

3. EXPERT REPORTS
The applicant has included detailed expert reports in Module 2 of the application. Signed declarations and copies of the experts' CVs are enclosed in Module 1.4 for the quality, non-clinical and clinical experts. All are considered to have sufficient experience for their responsibilities.

4. PRODUCT NAME & APPEARANCE
See 2.1 for details of the proposed product name. The appearance of the product is identical to the cross-reference product.

5. SUMMARY OF PRODUCT CHARACTERISTICS
The proposed summary is consistent with the details registered for the cross-reference product.

6. PATIENT INFORMATION LEAFLET/CARTON
PIL
The patient information leaflet has been prepared in-line with the details registered for the cross-reference product. The package leaflet has been submitted to the MHRA along with results of consultations with target patient groups ("user testing"), in accordance with Article 59 of Council Directive 2001/83/EC. The results indicate that the package leaflet is well-structured and organised, easy to understand and written in a comprehensive manner. The test shows that the patients/users are able to act upon the information that it contains.

Labelling
The proposed artwork is comparable to the artwork registered for the cross-reference product and complies with statutory requirements. In-line with current legislation, the applicant has also included the name of the product in Braille on the packaging.

7. CONCLUSIONS

The data submitted with the application is acceptable. The grant of a Marketing Authorisation is recommended.

PRECLINICAL ASSESSMENT

No new preclinical data have been supplied with this application and none are required for an application of this type.

CLINICAL ASSESSMENT

No new clinical data have been supplied with this application and none are required for an application of this type.

OVERALL CONCLUSION AND RISK BENEFIT ASSESSMENT

QUALITY

The data for this application is consistent with that previously assessed for the cross-reference product and, as such, has been judged to be satisfactory.

PRECLINICAL

No new preclinical data were submitted and none are required for applications of this type.

EFFICACY

This application is identical to a previously granted application Rennie Sugar Free (PL 00010/0362), which was originally approved to Bayer PLC on 1st July 2005.

No new or unexpected safety concerns arise from this application.

The SPC, PIL and labelling are satisfactory and consistent with that for the cross-reference product.

RISK BENEFIT ASSESSMENT

The quality of the product is acceptable and no new preclinical or clinical safety concerns have been identified. The applicant's product is identical to the cross-reference product. Extensive clinical experience with magnesium carbonate and calcium carbonate is considered to have demonstrated the therapeutic value of the compounds. The risk:benefit is, therefore, considered to be positive.

RENNIE ICE SUGAR FREE
PL 00010/0624

STEPS TAKEN FOR ASSESMENT

1	The MHRA received the marketing authorisation application on 9th December 2008.
2	Following standard checks and communication with the applicant the MHRA considered the applications valid on 30th December 2008.
3	Following assessment of the applications, the MHRA requested further information relating to the quality dossiers on 26th January 2009.
4	The applicant responded to the MHRA's requests, providing further information on 18th May 2009 for the quality sections.
5	The applications were determined on 19th May 2009.

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STEPS TAKEN AFTER ASSESSMENT

Date submitted	Application type	Scope	Outcome

RENNIE ICE SUGAR FREE
PL 00010/0624

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Rennie Ice Sugar Free

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Calcium carbonate	680 mg
Magnesium carbonate, heavy	80 mg

Also contains Sorbitol (E420)
For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Chewable tablet
A square white tablet with rounded corners, bevelled edges and concave faces, embossed 'Rennie' on both sides.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the relief of indigestion, heartburn, nervous indigestion, hyperacidity, flatulence, upset stomach, dyspepsia, biliousness, gastritis, overindulgence in food and drink, indigestion during pregnancy.

4.2 Posology and method of administration

Tablets to be taken orally, sucked or chewed.
Adults:
Two tablets to be sucked or chewed as required, to a maximum of sixteen tablets a day.

Elderly:
No special dosage regimen is required, but care should be taken to observe the contraindications and warnings.

Children:
Under 5 years: should only be taken on a doctor's advice.
5-8 years: 1 tablet as required, to a maximum of 6 tablets a day.
8-12 years: 1-2 tablets as required, to a maximum of 12 tablets a day.

4.3 Contraindications

Rennie Ice Sugar Free should not be administered to patients with:

- Severe renal function impairment
- Hypercalcaemia
- Hypersensitivity to the active ingredients or any of the excipients, refer to section 6.1

4.4 Special warnings and precautions for use

Prolonged use should be avoided.
Do not exceed the stated dose and if symptoms persist consult your doctor.

Caution should generally be exercised in the case of patients with impaired renal function. If Rennie Ice Sugar Free is used in such patients, plasma calcium and magnesium levels should be regularly monitered.

Long term uses at high doses can result in undesirable effects such as hypercalcaemia, hypermagnesaemia and milk-alkali syndrome, especially in patients with renal insufficency. Prolonged use possibly enhances the risk for the development of renal calculi.

Patients with rare hereditary problems of fructose intolerance, should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

Changes in gastric acidity, such as that caused by the ingestion of antacids, can affect the rate and degree to which some concurrently administered medicines are absorbed.

It has been shown that antacids which contain calcium or magnesium can impede the absorption of some antibiotics (such as tetracyclines and quinolones). Calcium and magnesium salts can also impede the absorption of phosphates.

Because of possible changes in the rates of absorption of concurrently administered medicines, it is recommended that antacids should not be taken concurrently with these medicines, but 1 to 2 hours later.

4.6 Pregnancy and lactation

Rennie Ice Sugar Free is part of the Rennie range of products which have been in clinical use, including use in pregnancy, since 1935. No adverse effects on pregnancy or the health of the foetus/newborn child have been reported, but there have been no specific epidemiological studies conducted to address this issue.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

Very rarely hypersensitivity reactions have been reported.

4.9 Overdose

Especially in patients with impaired renal function, prolonged use of high doses of Rennie Ice Sugar Free can result in renal insufficiency, milk alkali syndrome, hypermagnesaemia, hypercalcaemia and alkalosis which may give rise to gastrointestinal symptoms (nausea, vomiting, constipation) and abnormal muscular weakness. In such cases, the product should be withdrawn and adequate fluid intake encouraged.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic Classification: Antacids
ATC codes: Calcium carbonate: A02AC01
Magnesium carbonate: A02AA01

Calcium and magnesium carbonate react with excess acid in the gastric juice to produce soluble chlorides

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

Calcium carbonate has a rapid and powerful neutralising action. This effect is increased by the addition of magnesium carbonate which also has a strong neutralising action.
In healthy volunteers, a significant increase in the pH of stomach contents above baseline pH was achieved between 1 and 6 minutes after dosing.

5.2 Pharmacokinetic properties

A small amount of calcium and magnesium may be absorbed, but in healthy subjects it is usually rapidly excreted by the kidney. The soluble chlorides produced by the reaction of calcium and magnesium with gastric acid react, in turn, with intestinal, biliary and pancreatic secretions to form insoluble salts, which are excreted in the faeces.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber, which are additional to those already included in other sections of the SmPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sorbitol (E420)

Potato starch
Maize starch pregelatinised
Magnesium stearate
Talc
Liquid paraffin
Saccharin sodium
Spearmint flavour - consists of: mint oils (mentha spicata and mentha piperita), maltodextrin, acacia, silicon dioxide

6.2 Incompatibilities
None

6.3 Shelf life
Blister packs: 36 months
Roll wraps: 24 months

6.4 Special precautions for storage
Blister packs: Do not store above 25°C. Protect from moisture.
Roll wraps: Protect from moisture.

6.5 Nature and contents of container
Tablets are packed in aluminium foil/pvc bubble packs with six or twelve tablets per strip.
3, 4, 6 or 8 strips are packed in a cardboard carton. The foil is printed with the name "Rennie Ice Sugar free".

12 tablet Pocket Pack - Tablets are packed in a hard tempered aluminium foil (20µm)/clear thermoformable PVC (250µm) bubble pack, with six tablets per strip. Two strips are packed in a cardboard pocket pack.

12 tablet pack tablets are roll wrapped in laminated foil.
Pack sizes: 12, 24, 36, 48, 72, 96.

6.6 Special precautions for disposal
No special precautions necessary.

7 MARKETING AUTHORISATION HOLDER
Bayer plc, Consumer Care Division
Bayer House
Strawberry Hill
Newbury
Berkshire
RG14 1JA
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)
PL 00010/0624

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
19/05/2009

10 DATE OF REVISION OF THE TEXT
19/05/2009

Rennie ICE SUGAR FREE

Calcium carbonate, Magnesium carbonate

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

This medicine is available without prescription. However, you still need to take Rennie Ice Sugar Free tablets carefully to get the best results from them. Keep this leaflet, you may need to read it again. Ask your pharmacist if you need more information or advice. You must contact a doctor if your symptoms worsen or do not improve. If you have any unusual effects after taking Rennie Ice Sugar Free, tell your doctor or pharmacist.

IN THIS LEAFLET

1. WHAT IS RENNIE ICE SUGAR FREE AND WHAT IS IT USED FOR?

Rennie Ice Sugar Free is a mint flavour antacid tablet which quickly relieves indigestion, heartburn, acid indigestion, dyspepsia, hyperacidity, gastritis, nervous indigestion, flatulence, upset stomach, indigestion during pregnancy and biliousness.

2. BEFORE YOU TAKE RENNIE ICE SUGAR FREE

Do not take Rennie Ice Sugar Free:

- If you have severe kidney disease.
- If you have high calcium levels in the blood.
- If you are allergic (hypersensitive) to any of the ingredients (*listed in Section 6. Further Information*).

Special precautions:

Do not exceed the stated dose.

Rennie Ice Sugar Free should not be used for a prolonged period without consulting a doctor.

Please consult your doctor or pharmacist if you have any kidney problems.

This product contains sorbitol (E420). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

If symptoms persist consult your doctor.

Taking other medicines:

- Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.
- If you are taking antibiotics (tetracyclines, quinolones) speak to your doctor or pharmacist before taking Rennie Ice Sugar Free because it can affect how these medicines work.
- To maximise the benefit of all medicines being used, take Rennie Ice Sugar Free 1 to 2 hours after taking any other medicines.

3. HOW TO TAKE RENNIE ICE SUGAR FREE

Adults: 2 tablets to be sucked or chewed as required, up to a maximum of 16 tablets a day.

Children 8-12 years: 1-2 tablets as required, up to a maximum of 12 tablets a day.

Children 5-8 years: 1 tablet as required, up to a maximum of 6 tablets a day.

Children under 5: Not recommended.

Pregnancy and breast-feeding:

Rennie Ice Sugar Free can be used during pregnancy and breastfeeding if taken as instructed.

If you take more Rennie Ice Sugar Free than you should:

Drink plenty of water and consult your doctor or pharmacist. Symptoms of an overdose include nausea and vomiting, tiredness, increased urine production, increased thirst, dehydration and abnormal muscular weakness.

If you have any questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Rennie Ice Sugar Free can cause side effects, although not everybody gets them. Side effects are unlikely at the recommended dose.

Very rarely, rashes, swelling or shortness of breath may occur. If you experience these or any other unusual side effect after taking these tablets you should seek the advice of a doctor or pharmacist.

5. HOW TO STORE RENNIE ICE SUGAR FREE

Keep out of the reach and sight of children.

Protect from moisture.

Do not use Rennie Ice Sugar Free after the expiry date which is stated on the carton and roll. The expiry date refers to the last day of that month.

Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Rennie Ice Sugar Free contains:

Each tablet contains the active ingredients: calcium carbonate 680mg and heavy magnesium carbonate 80mg.

The other ingredients are sorbitol (E420), magnesium stearate, potato starch, pregelatinised maize starch, talc, spearmint flavour, liquid paraffin, saccharin sodium.

What Rennie Ice Sugar Free looks like and the contents of the pack:

Rennie Ice Sugar Free are cream white square tablets, engraved "RENNIE" on both faces.

Rennie Ice Sugar Free are available in packs of 12, 24, 36, 48, 72, 96 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

Marketing Authorisation Holder: Bayer plc, Consumer Care division, Bayer House, Strawberry Hill, Newbury, Berkshire, RG14 1JA, UK. consumer.care@bayer.co.uk

Manufacturer: Bayer Santé Familiale, 74240 Gaillard, France.

This leaflet was last revised in: December 2008

Bayer

Marketing Authorisation Holder and Manufacturer:

Marketing Authorisation Holder: Bayer plc, Consumer Care division, Bayer House,

Strawberry Hill, Newbury, Berkshire, RG14 IJA, UK.

consumer.care@bayer.co.uk

Manufacturer: Brecon Pharmaceuticals Ltd., Pharos House, Wye Valley Business Park, Hay-on-Wye, Hereford, HR3 5PG.

This leaflet was last revised in: December 2008

Bayer

Rennie

ICE SUGAR FREE

Calcium carbonate, Magnesium carbonate

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

BAYER

Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Rennie Ice Sugar Free contains:

Each tablet contains the active ingredients: calcium carbonate 680mg and heavy magnesium carbonate 80mg.

The other ingredients are sorbitol (E420), magnesium stearate, potato starch, pregelatinised maize starch, talc, spearmint flavour, liquid paraffin, saccharin sodium.

IN THIS LEAFLET

1. WHAT IS RENNIE ICE SUGAR FREE AND WHAT IS IT USED FOR?

Rennie Ice Sugar Free is a mint flavour antacid tablet

If you take more Rennie Ice Sugar Free than you should:

Drink plenty of water and consult your doctor or pharmacist. Symptoms of an overdose include nausea and vomiting, tiredness, increased urine production, increased thirst, dehydration and abnormal muscular weakness.

If you have any questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Rennie Ice Sugar Free can cause side effects, although not everybody gets them. Side effects are unlikely at the recommended dose.

Special precautions:

Do not exceed the stated dose.

Rennie Ice Sugar Free should not be used for a prolonged period without consulting a doctor.

Please consult your doctor or pharmacist if you have any kidney problems.

This product contains sorbitol (E420). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

If symptoms persist consult your doctor.

This medicine is available without prescription. However, you still need to take Rennie Ice Sugar Free tablets carefully to get the best results from them. Keep this leaflet, you may need to read it again. Ask your pharmacist if you need more information or advice. You must contact a doctor if your symptoms worsen or do not improve. If you have any unusual effects after taking Rennie Ice Sugar Free, tell your doctor or pharmacist.

What Rennie Ice Sugar Free looks like and the contents of the pack:

Rennie Ice Sugar Free are cream white square tablets, engraved "RENNIE" on both faces.

Rennie Ice Sugar Free are available in packs of 12, 24, 36, 48, 72, 96 tablets. Not all pack sizes may be marketed.

which quickly relieves indigestion, heartburn, acid indigestion, dyspepsia, hyperacidity, gastritis, nervous indigestion, flatulence, upset stomach, indigestion during pregnancy and biliousness.

2. BEFORE YOU TAKE RENNIE ICE SUGAR FREE

Do not take Rennie Ice Sugar Free:

- If you have severe kidney disease.
- If you have high calcium levels in the blood.
- If you are allergic (hypersensitive) to any of the ingredients (*listed in Section 6. Further Information*).

Very rarely, rashes, swelling or shortness of breath may occur. If you experience these or any other unusual side effect after taking these tablets you should seek the advice of a doctor or pharmacist.

5. HOW TO STORE RENNIE ICE SUGAR FREE

Keep out of the reach and sight of children.

Do not store above 25°C and protect from moisture.

Do not use Rennie Ice Sugar Free after the expiry date which is stated on the carton and blister. The expiry date refers to the last day of that month.

Taking other medicines:

- Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.
- If you are taking antibiotics (tetracyclines, quinolones) speak to your doctor or pharmacist before taking Rennie Ice Sugar Free because it can affect how these medicines work.
- To maximise the benefit of all medicines being used, take Rennie Ice Sugar Free 1 to 2 hours after taking any other medicines.

3. HOW TO TAKE RENNIE ICE SUGAR FREE

Adults: 2 tablets to be sucked or chewed as required, up to a maximum of 16 tablets a day.

Children 8-12 years: 1-2 tablets as required, up to a maximum of 12 tablets a day.

Children 5-8 years: 1 tablet as required, up to a maximum of 6 tablets a day.

Children under 5: Not recommended.

Pregnancy and breast-feeding:

Rennie Ice Sugar Free can be used during pregnancy and breastfeeding if taken as instructed.

Rennie ICE SUGAR FREE

Calcium carbonate, Magnesium carbonate

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

This medicine is available without prescription. However, you still need to take Rennie Ice Sugar Free tablets carefully to get the best results from them. Keep this leaflet, you may need to read it again. Ask your pharmacist if you need more information or advice. You must contact a doctor if your symptoms worsen or do not improve. If you have any unusual effects after taking Rennie Ice Sugar Free, tell your doctor or pharmacist.

IN THIS LEAFLET

1. WHAT IS RENNIE ICE SUGAR FREE AND WHAT IS IT USED FOR?

Rennie Ice Sugar Free is a mint flavour antacid tablet which quickly relieves indigestion, heartburn, acid indigestion, dyspepsia, hyperacidity, gastritis, nervous indigestion, flatulence, upset stomach, indigestion during pregnancy and biliousness.

2. BEFORE YOU TAKE RENNIE ICE SUGAR FREE

Do not take Rennie Ice Sugar Free:

- If you have severe kidney disease.
- If you have high calcium levels in the blood.
- If you are allergic (hypersensitive) to any of the ingredients (*listed in Section 6. Further Information*).

Special precautions:

Do not exceed the stated dose.
Rennie Ice Sugar Free should not be used for a prolonged period without consulting a doctor.
Please consult your doctor or pharmacist if you have any kidney problems.
This product contains sorbitol (E420). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
If symptoms persist consult your doctor.

Taking other medicines:

- Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.
- If you are taking antibiotics (tetracyclines, quinolones) speak to your doctor or pharmacist before taking Rennie Ice Sugar Free because it can affect how these medicines work.
- To maximise the benefit of all medicines being used, take Rennie Ice Sugar Free 1 to 2 hours after taking any other medicines.

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3. HOW TO TAKE RENNIE ICE SUGAR FREE

Adults: 2 tablets to be sucked or chewed as required, up to a maximum of 16 tablets a day.

Children 8-12 years: 1-2 tablets as required, up to a maximum of 12 tablets a day.

Children 5-8 years: 1 tablet as required, up to a maximum of 6 tablets a day.

Children under 5: Not recommended.

Pregnancy and breast-feeding:
Rennie Ice Sugar Free can be used during pregnancy and breastfeeding if taken as instructed.

If you take more Rennie Ice Sugar Free than you should:
Drink plenty of water and consult your doctor or pharmacist. Symptoms of an overdose include nausea and vomiting, tiredness, increased urine production, increased thirst, dehydration and abnormal muscular weakness.

If you have any questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Rennie Ice Sugar Free can cause side effects, although not everybody gets them. Side effects are unlikely at the recommended dose.

Very rarely, rashes, swelling or shortness of breath may occur. If you experience these or any other unusual side effect after taking these tablets you should seek the advice of a doctor or pharmacist.

5. HOW TO STORE RENNIE ICE SUGAR FREE

Keep out of the reach and sight of children.
Do not store above 25°C and protect from moisture.
Do not use Rennie Ice Sugar Free after the expiry date which is stated on the carton and blister. The expiry date refers to the last day of that month.

Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Rennie Ice Sugar Free contains:
Each tablet contains the active ingredients: calcium carbonate 680mg and heavy magnesium carbonate 80mg.

The other ingredients are sorbitol (E420), magnesium stearate, potato starch, pregelatinised maize starch, talc, spearmint flavour, liquid paraffin, saccharin sodium.

What Rennie Ice Sugar Free looks like and the contents of the pack:
Rennie Ice Sugar Free are cream white square tablets, engraved "RENNIE" on both faces.

Rennie Ice Sugar Free are available in packs of 12, 24, 36, 48, 72, 96 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:
Marketing Authorisation Holder: Bayer plc,
Consumer Care division, Bayer House,
Strawberry Hill, Newbury, Berkshire, RG14 1JA, UK.
consumer.care@bayer.co.uk
Manufacturer: Bayer Santé Familiale, 74240 Gaillard, France.
This leaflet was last revised in: December 2008

Bayer

Rennie ICE SUGAR FREE

Calcium carbonate, Magnesium carbonate

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This product contains sorbitol (E420). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

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Taking other medicines:

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- If you are taking antibiotics (tetracyclines, quinolones) speak to your doctor or pharmacist before taking Rennie Ice Sugar Free because it can affect how these medicines work.
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3. HOW TO TAKE RENNIE ICE SUGAR FREE

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Children 8-12 years: 1-2 tablets as required, up to a maximum of 12 tablets a day.

Children 5-8 years: 1 tablet as required, up to a maximum of 6 tablets a day.

Children under 5: Not recommended.

Pregnancy and breast-feeding:

Rennie Ice Sugar Free can be used during pregnancy and breastfeeding if taken as instructed.

If you take more Rennie Ice Sugar Free than you should:

Drink plenty of water and consult your doctor or pharmacist. Symptoms of an overdose include nausea and vomiting, tiredness, increased urine production, increased thirst, dehydration and abnormal muscular weakness.

If you have any questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Rennie Ice Sugar Free can cause side effects, although not everybody gets them. Side effects are unlikely at the recommended dose.

Very rarely, rashes, swelling or shortness of breath may occur. If you experience these or any other unusual side effect after taking these tablets you should seek the advice of a doctor or pharmacist.

5. HOW TO STORE RENNIE ICE SUGAR FREE

Keep out of the reach and sight of children.

Do not store above 25°C and protect from moisture.

Do not use Rennie Ice Sugar Free after the expiry date which is stated on the carton and blister. The expiry date refers to the last day of that month.

Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Rennie Ice Sugar Free contains:

Each tablet contains the active ingredients: calcium carbonate 680mg and heavy magnesium carbonate 80mg.

The other ingredients are sorbitol (E420), magnesium stearate, potato starch, pregelatinised maize starch, talc, spearmint flavour, liquid paraffin, saccharin sodium.

What Rennie Ice Sugar Free looks like and the contents of the pack:

Rennie Ice Sugar Free are cream white square tablets, engraved "RENNIE" on both faces.

Rennie Ice Sugar Free are available in packs of 12, 24, 36, 48, 72, 96 tablets. Not all pack sizes may be marketed.

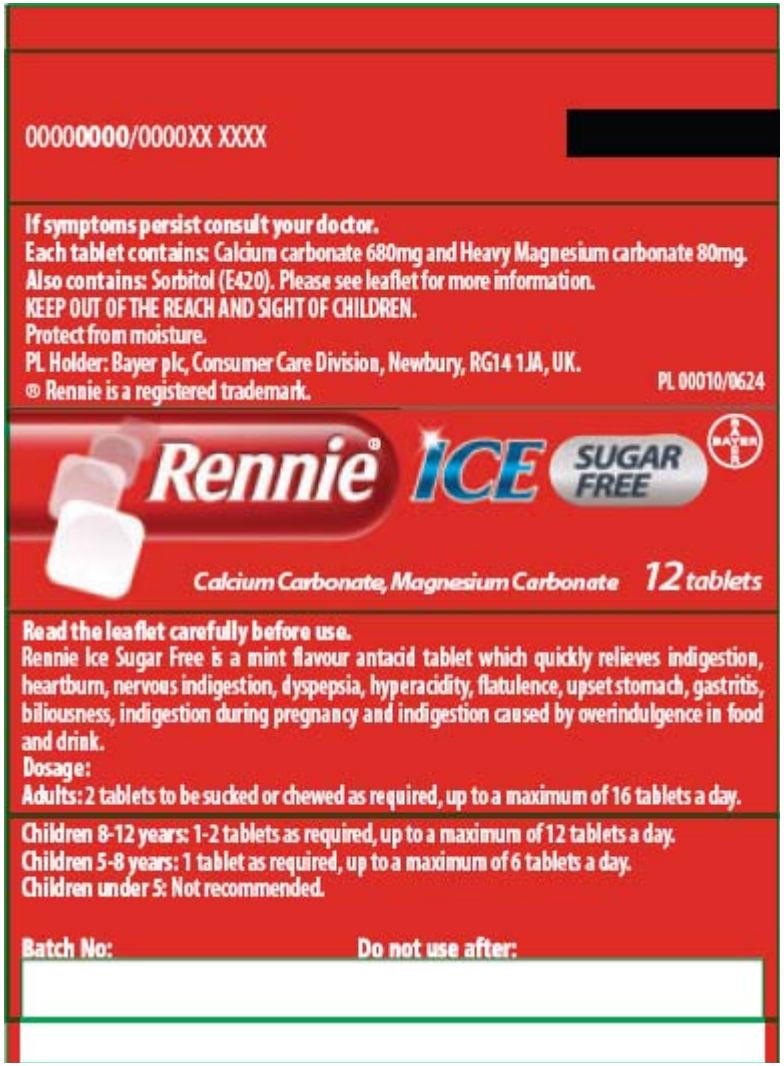
Marketing Authorisation Holder and Manufacturer:

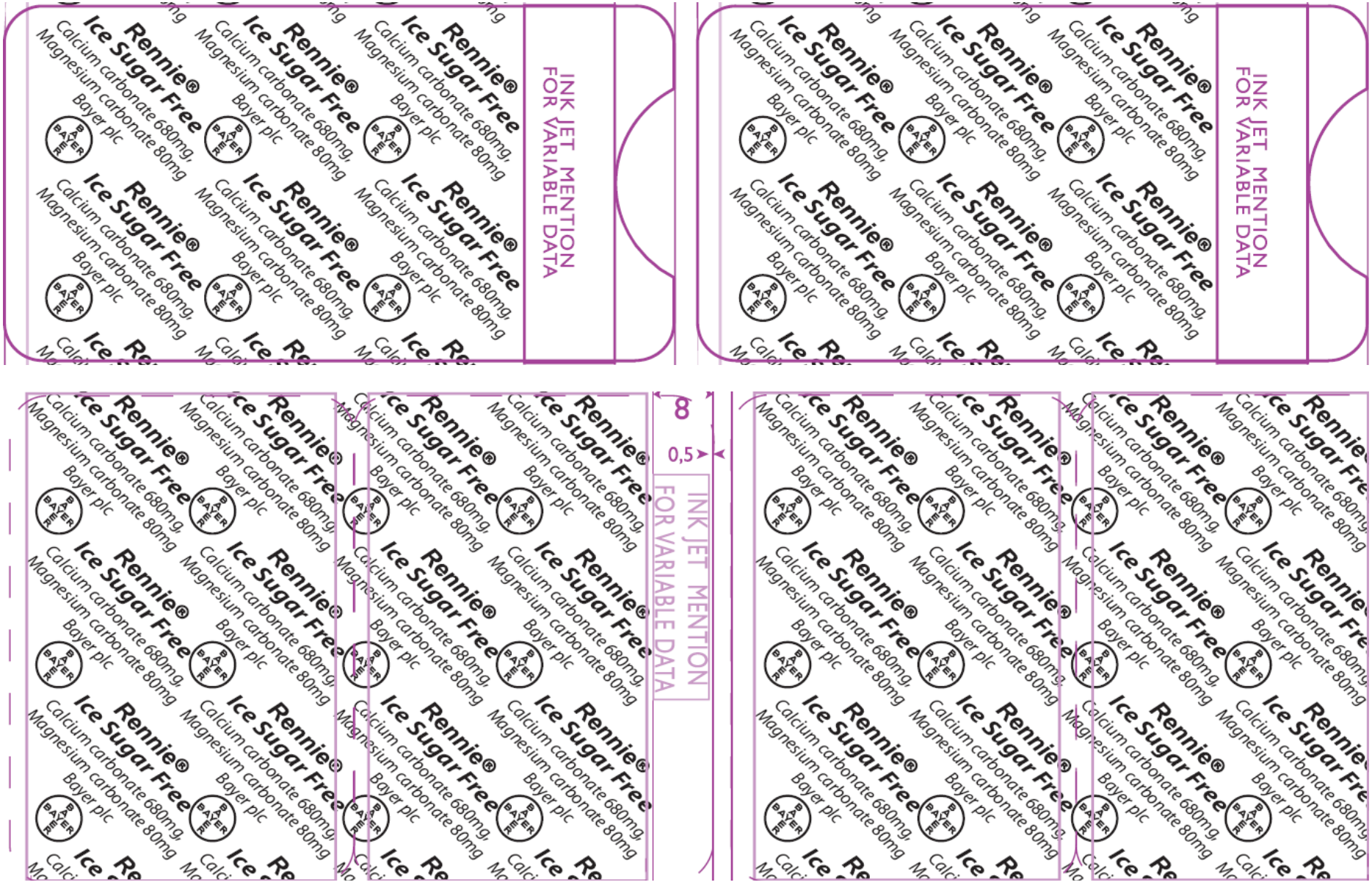
Marketing Authorisation Holder: Bayer plc, Consumer Care division, Bayer House, Strawberry Hill, Newbury, Berkshire, RG14 IJA, UK.
consumer.care@bayer.co.uk
Manufacturer: Bayer Santé Familiale, 74240 Gaillard, France.

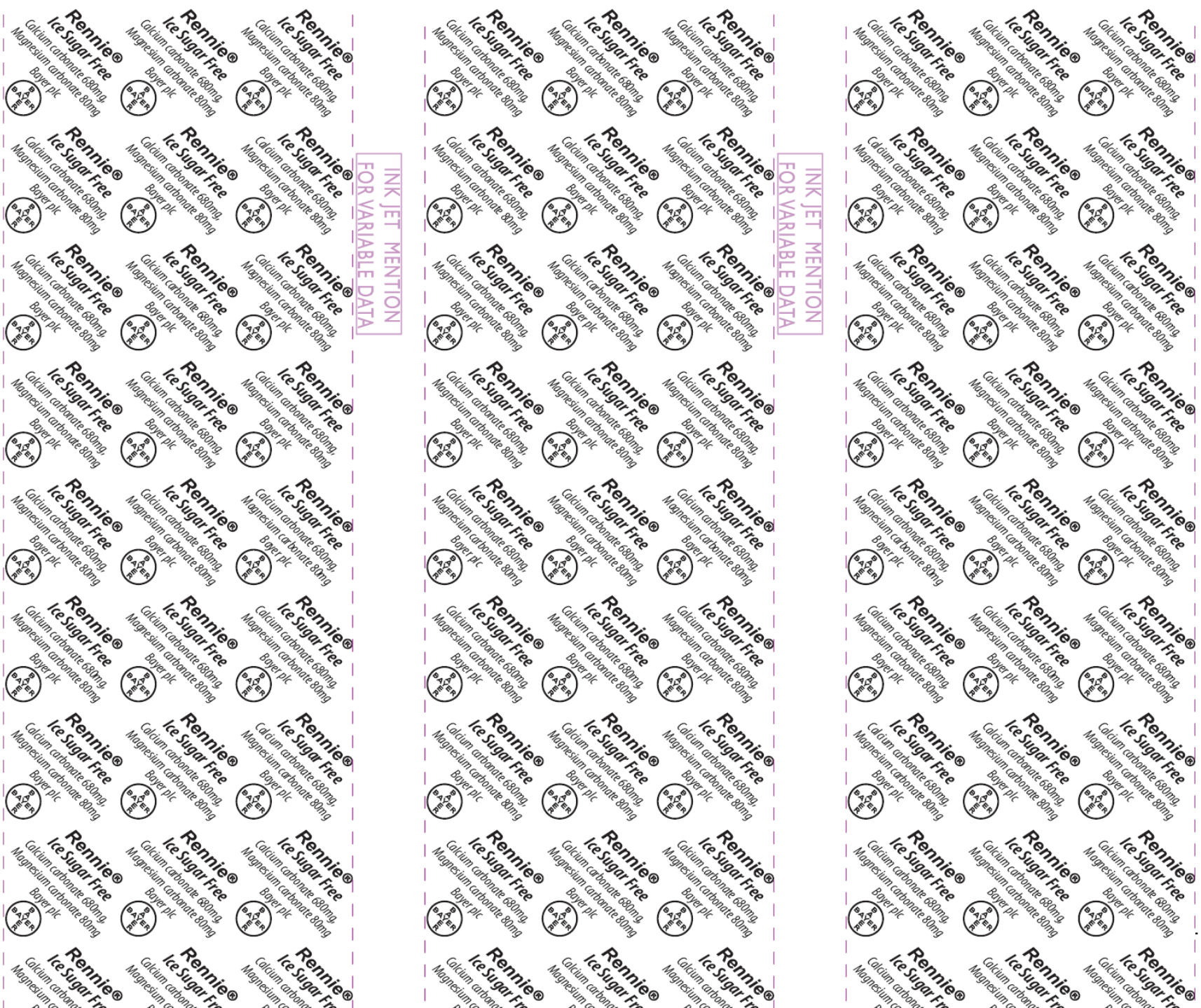
This leaflet was last revised in: December 2008

Bayer

The labelling below is the label agreed at the end of the procedure for the 12 tablet pocket pack and the packs rolled in laminate foil in sizes 12, 24, 36 and 48. The marketing authorisation holder has stated that it is not intending to market the product in pack sizes 72 and 96 and, thus, no mock-up documents have been submitted. The marketing authorisation holder has committed to submit the UK PIL and labelling for review to the regulatory authority before marketing either pack size.




Rennie®
Ice Sugar Free
Calcium carbonate 680mg,
Magnesium carbonate 80mg
Bayer plc
INK JET MENTION
FOR VARIABLE DATA
8
0,5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