Rennie Fresh 680 mg / 80 mg chewable tablets
(calcium carbonate and heavy magnesium carbonate)

PL 00010/0650

UKPAR

TABLE OF CONTENTS

Lay Summary ............................................................... Page 2
Scientific Discussion ...................................................... Page 4
Steps Taken for Assessment ............................................. Page 11
Steps taken after authorisation - summary ....................... Page 12
Summary of Product Characteristics ............................... Page 13
Patient Information Leaflet ............................................. Page 14
Labelling ........................................................................ Page 15
LAY SUMMARY

Rennie Fresh 680 mg / 80 mg chewable tablets
(calcium carbonate and heavy magnesium carbonate; 680 mg/80 mg; chewable tablets)

This is a summary of the Public Assessment Report (PAR) for Rennie Fresh 680 mg / 80 mg chewable tablets (PL 00010/0650). It explains how the application for Rennie Fresh 680 mg / 80 mg chewable tablets was assessed and its authorisation recommended, as well as the conditions of use. It is not intended to provide practical advice on how to use Rennie Fresh 680 mg / 80 mg chewable tablets.

For practical information about using Rennie Fresh 680 mg / 80 mg chewable tablets, patients should read the package leaflet or contact their doctor or pharmacist.

The product may be referred to as Rennie Fresh in this report.

What is Rennie Fresh and what is it used for?
This medicine is the same as Rennie Ice (PL 00010/0349), which is already authorised in the UK. The licence holder (Bayer plc) for Rennie Ice (PL 00010/0349) has agreed that its own scientific data can be used as a basis for the grant of an identical licence for Rennie Fresh (informed consent).

Rennie Fresh is an antacid. It is used in adults and children over 12 years of age to quickly relieve indigestion, heartburn, acid indigestion, dyspepsia, hyperacidity, nervous indigestion, flatulence, upset stomach, indigestion during pregnancy and biliousness.

How does Rennie Fresh work?
Rennie Fresh contains the active ingredients calcium carbonate and heavy magnesium carbonate, which neutralise excess acid in the stomach.

How is Rennie Fresh used?
Rennie Fresh is available as chewable tablets and is taken by mouth.

The recommended dosage in adults and children over 12 years of age: 2 tablets should be sucked or chewed as required, preferably 1 hour after meals and before bedtime. For heartburn an extra 2 tablets may be taken between these times. The patient should not take more than 10 tablets a day. Rennie Fresh is not recommended in children under 12 years.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

Rennie Fresh can be obtained without a prescription, at pharmacies, supermarkets and other retail outlets without the supervision of a pharmacist.

What benefits of Rennie Fresh has been shown in studies?
The application for Rennie Fresh is considered to be identical to the previously authorised licence for Rennie Ice (PL 00010/0349; Bayer plc), with the same benefits and risks. So, no new studies have been provided for Rennie Fresh. However, reference is made to the studies for Rennie Ice (PL 00010/0349; Bayer plc).

What are the possible side effects from Rennie Fresh?
Like all medicines, Rennie Fresh can cause side effects, although not everybody gets them.

For the full list of all side effects reported with Rennie Fresh, see section 4 of the package leaflet.
For the full list of restrictions, see the package leaflet.

**Why is Rennie Fresh approved?**
No new or unexpected safety concerns arose from this application. The MHRA, therefore, considered that the benefits of Rennie Fresh outweigh their risks; and the grant of a Marketing Authorisation was recommended.

**What measures are being taken to ensure the safe and effective use of Rennie Fresh?**
A Risk Management Plan has been developed to ensure that Rennie Fresh is used as safely as possible. Based on this plan, safety information has been included in the Summary of Product Characteristics and the package leaflet for Rennie Fresh, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously.

**Other information about Rennie Fresh 680 mg/ 80 mg chewable tablets.**
A Marketing Authorisation was granted in the UK on 08 April 2015.

The full PAR for Rennie Fresh 680 mg/ 80 mg chewable tablets follows this summary.

For more information about treatment with Rennie Fresh 680 mg/ 80 mg chewable tablets, read the package leaflet, or contact your doctor or pharmacist.

This summary was last updated in June 2015.
Rennie Fresh 680 mg / 80 mg chewable tablets
(calcium carbonate and heavy magnesium carbonate)

PL 00010/0650

SCIENTIFIC DISCUSSION

TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Introduction</td>
<td>5</td>
</tr>
<tr>
<td>Pharmaceutical assessment</td>
<td>6</td>
</tr>
<tr>
<td>Non-clinical assessment</td>
<td>8</td>
</tr>
<tr>
<td>Clinical assessment</td>
<td>9</td>
</tr>
<tr>
<td>Overall conclusion and benefit/risk assessment</td>
<td>10</td>
</tr>
</tbody>
</table>
INTRODUCTION

The Medicines and Healthcare products Regulatory Agency (MHRA) granted Bayer plc a Marketing Authorisation for the medicinal product Rennie Fresh 680 mg / 80 mg chewable tablets (PL 00010/0650) on 08 April 2015. The product is a General Sales Licence (GSL) medicine indicated for the relief of indigestion, heartburn, nervous indigestion, hyperacidity, flatulence, upset stomach, dyspepsia, biliousness, overindulgence in food and drink and indigestion during pregnancy.

The application was submitted as an abridged application according to Article 10c of Directive 2001/83/EC, as amended, cross-referring to Rennie Ice (PL 00010/0349; Bayer plc), which was authorised in 2005. Rennie Ice (PL 00010/0349; Bayer plc) was authorised after a series of change of ownership, informed consent or default conversion applications from PL 00031/0409 (on 03 February 1997), PL 00188/0135 (on 19 October 1993), PL 00188/5901R (on 25 February 1991) and from the original Marketing Authorisation, PLR 00139/5003, granted to Nicholas Products Limited in January 1982.

Rennie Fresh 680 mg / 80 mg chewable tablets contain the active ingredients calcium carbonate and heavy magnesium carbonate. Calcium and magnesium carbonates react with excess acid in the gastric medium to produce soluble chlorides. 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.

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

LICENCE NO: PL 00010/0650
PROPRIETARY NAME(S): Rennie Fresh 680 mg / 80 mg chewable tablets
ACTIVE(S): Calcium carbonate and heavy magnesium carbonate
COMPANY NAME: Bayer plc
E.C. ARTICLE: Article 10c of Directive 2001/83/EC, as amended
LEGAL STATUS: GSL

1. INTRODUCTION
This is an abridged application for Rennie Fresh 680 mg / 80 mg chewable tablets (PL 00010/0650) submitted under Article 10c of Directive 2001/83/EC, as amended.

The application cross-refers to Rennie Ice (PL 00010/0349; Bayer), which was granted a Marketing Authorisation in the UK to Bayer plc in 2005. The application is considered valid.

2. MARKETING AUTHORISATION APPLICATION FORM
2.1. Name
The proposed name of the product is Rennie Fresh 680 mg / 80 mg chewable tablets. The product has been named in line with current requirements.

2.2. Strength, pharmaceutical form, route of administration, container and pack sizes
Each chewable tablet contains 680 mg of calcium carbonate and 80 mg of heavy magnesium carbonate.

The product is packaged in:
1. hard tempered aluminium foil (20µm)/clear thermoformable polyvinylchloride (PVC) (150µm) bubble packs, with six or twelve tablets per strip. 1, 3, 4, 6 or 8 strips are packed in a cardboard carton.
2. 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.

The product is available in pack sizes of 6, 12, 24, 36, 48, 72 and 96 chewable tablets. Not all pack sizes may be marketed.

The proposed shelf life for the product is 36 months, with the special storage conditions ‘Do not store above 25°C’. The packaging, proposed shelf-life and storage conditions are consistent with the details registered for the cross reference product.

2.3. Legal status
On approval, the product will be available as a General Sales Licence (GSL) medicine.

2.4. Marketing Authorisation Holder/Contact Persons/Company
Bayer plc, Consumer Care Division, Bayer House, Strawberry Hill, Newbury, Berkshire, RG14 1JA, UK

The Qualified Person (QP) responsible for pharmacovigilance is stated and a satisfactory CV has been provided.

2.5 Manufacturers
The proposed manufacturing sites are consistent with those registered for the cross-reference product and evidence of Good Manufacturing Practice (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 sizes are stated.

2.8. Finished product/shelf-life specification
The proposed finished product specification is consistent 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
None of the excipients contain materials of animal or human origin. This is consistent with the cross-reference product.

2.11. Bioequivalence
No bioequivalence data are required to support this simple abridged application because the proposed product is manufactured to the same formula and utilises the same processes as the reference product Rennie Ice (PL 00010/0349; Bayer plc).

3. EXPERT REPORT
The applicant cross-refers to the data for Rennie Ice (PL 00010/0349; Bayer plc), to which this application is claimed to be identical. This is acceptable.

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

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

6. PATIENT INFORMATION LEAFLET (PIL) AND LABELLING
PIL
The PIL has been prepared in line with the details registered for the cross-reference product.

Carton and label
The proposed text is consistent with that for the cross-reference product. The Marketing Authorisation holder has committed to submitting mock-ups to the relevant regulatory authorities for approval before marketing any pack size.

7. CONCLUSION
The data submitted with the application is acceptable. The grant of a Marketing Authorisation is recommended.
NON-CLINICAL ASSESSMENT

As this is an abridged application submitted under Article 10c of Directive 2001/83/EC, as amended, no new non-clinical data have been supplied and none are required.

Suitable justification has been provided for non-submission of an Environmental Risk Assessment. As the application is an identical version of an already authorised product, it is not expected that environmental exposure will increase following approval of the Marketing Authorisation for the proposed product.

The grant of a Marketing Authorisation is recommended.
CLINICAL ASSESSMENT

As this is an abridged application submitted under Article 10c of Directive 2001/83/EC, as amended, no new clinical data have been supplied and none are required.

The Marketing Authorisation Holder has provided details of a suitable pharmacovigilance system that fulfils the requirements and provides adequate evidence that they have the services of a qualified person responsible for pharmacovigilance, and have the necessary means for the notification of any adverse reaction suspected of occurring either in the Community or in a third country.

An acceptable Risk Management Plan (RMP) has been submitted. Routine risk minimisation is provided through the Summary of Product Characteristics and the Patient Information Leaflet and this is sufficient.

The grant of a Marketing Authorisation is recommended.
OVERALL CONCLUSION AND BENEFIT/RISK ASSESSMENT

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

NON-CLINICAL
No new non-clinical data were submitted and none are required for this type of application.

EFFICACY
This application is identical to the previously granted licence for Rennie Ice (PL 00010/0349; Bayer plc).

SAFETY
No new safety data were supplied or required for this application. Calcium carbonate and heavy magnesium carbonate have well-established safety profiles. No new or unexpected safety concerns arose from this application.

PRODUCT LITERATURE
The SmPC and PIL text are satisfactory, and consistent with those for the cross-reference product. The labelling text complies with statutory requirements and is satisfactory.

BENEFIT/RISK ASSESSMENT
The quality of the product is acceptable, and no new non-clinical or clinical safety concerns have been identified. The applicant’s product is identical to the cross-reference product. Extensive clinical experience with calcium carbonate and heavy magnesium carbonate is considered to have demonstrated the therapeutic value of the compounds. The benefit/risk assessment is, therefore, considered to be positive.
Rennie Fresh 680 mg / 80 mg chewable tablets
(calculator carbonate and heavy magnesium carbonate)

PL 00010/0650

STEPS TAKEN FOR ASSESSMENT

1. The MHRA received the Marketing Authorisation application on 23 June 2014.
2. Following standard checks and communication with the applicant the MHRA considered the application valid on 04 July 2014.
3. Following assessment of the application the MHRA requested further information relating to the dossier on 10 October 2014 and 15 December 2014.
4. The applicant responded to the MHRA’s request, providing further information on the 21 November 2014 and 25 February 2015.
5. The application was granted on 08 April 2015.
**Rennie Fresh 680 mg / 80 mg chewable tablets**
(calculator carbonate and heavy magnesium carbonate)

**PL 00010/0650**

**STEPS TAKEN AFTER AUTHORISATION - SUMMARY**

<table>
<thead>
<tr>
<th>Date submitted</th>
<th>Application type</th>
<th>Scope</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
SUMMARY OF PRODUCT CHARACTERISTICS

In accordance with Directive 2010/84/EU, the Summaries of Product Characteristics (SmPCs) for products granted Marketing Authorisations at a national level are available on the MHRA website.
PATIENT INFORMATION LEAFLET

In accordance with Directive 2010/84/EU, the Patient Information Leaflets (PILs) for products granted Marketing Authorisations at a national level are available on the MHRA website.
UKPAR Rennie Fresh 680 mg / 80 mg chewable tablets

PL 00010/0650