GAVISCON MINT FLAVOUR LIQUID
PL 00063/0604

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LAY SUMMARY

The MHRA granted Reckitt Benckiser Healthcare (UK) Limited a Marketing Authorisation (licence) for the medicinal product Gaviscon Mint Flavour Liquid on 10th March 2009. This product is indicated for the relief of heartburn and acid indigestion.

This product, to be available on a general-sales licence (GSL), contains sodium hydrogen carbonate, sodium alginate and calcium carbonate. This product forms a protective barrier over the stomach contents to soothe the burning pain in the chest (heartburn).

This application is a duplicate of a previously granted application for Gaviscon Cool Mint liquid (PL 00063/0158), which was originally approved to Reckitt Benckiser Healthcare (UK) Limited on 13th November 2008.

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

GAVISCON MINT FLAVOUR LIQUID
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SCIENTIFIC DISCUSSION

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INTRODUCTION

The UK granted Reckitt Benckiser Healthcare (UK) Limited a marketing authorisation for the medicinal product Gaviscon Mint Flavour Liquid (PL 00063/0604) on 10th March 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 Gaviscon Cool Mint liquid (PL 00063/0158), which was originally approved to Reckitt Benckiser Healthcare (UK) Limited on 13th November 2008.

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

This suspension contains the active ingredients sodium alginate, sodium bicarbonate and calcium carbonate and is indicated for the treatment of gastro-oesophageal reflux such as acid regurgitation, heartburn and indigestion, for example, following meals or during pregnancy.

PHARMACEUTICAL ASSESSMENT

LICENCE NO:	PL 00063/0604
PROPRIETARY NAME:	Gaviscon Mint Flavour Liquid
ACTIVE(S):	Sodium alginate, sodium hydrogen carbonate and calcium carbonate
COMPANY NAME:	Reckitt Benckiser Healthcare (UK) Limited
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 Gaviscon Mint Flavour Liquid (PL 00063/0604) submitted under Article 10c (formerly Article 10.1(a)(i)) of Directive 2001/83/EC. The proposed MA holder is Reckitt Benckiser Healthcare (UK) Limited, Dansom Lane, Hull, HU8 7DS, East Yorkshire, United Kingdom.

The application cross-refers Gaviscon Cool Mint liquid (PL 00063/0158), which was originally approved to Reckitt Benckiser Healthcare (UK) Limited on 13th November 2008.

The current application is considered valid.

2. MARKETING AUTHORISATION APPLICATION FORM

2.1 Name(s)

The proposed name of the product is Gaviscon Mint Flavour Liquid. The product has been named in-line with current requirements.

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

The product contains sodium alginate, sodium hydrogen carbonate and calcium carbonate. The finished product is packaged in Amber glass bottles, sealed with a polypropylene cap and a polyethylene tamper-evident band (lined with expanded polyethylene wad). Pack sizes are 100ml, 150ml, 200ml, 300ml, 500ml or 600 ml.
The proposed shelf-life (two years) and storage conditions (Do not store above 30°C. Do not refrigerate or freeze) 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

Reckitt Benckiser Healthcare (UK) Limited, Dansom Lane, Hull, HU8 7DS, East Yorkshire, 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 they contain.

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 and has included sufficient space for a standard UK pharmacy dispensing label.

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 Gaviscon Cool Mint liquid (PL 00063/0158), which was originally approved to Reckitt Benckiser Healthcare (UK) Limited on 13th November 2008.

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 sodium alginate, sodium hydrogen carbonate and calcium carbonate is considered to have demonstrated the therapeutic value of the compounds. The risk:benefit is, therefore, considered to be positive.

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STEPS TAKEN FOR ASSESMENT

1	The MHRA received the marketing authorisation applications on 16/02/2009.
2	Following standard checks and communication with the applicant the MHRA considered the application valid on 24/02/2009.
3	Following assessment of the application no further information was requested.
4	The applications were determined on 25/02/2009.

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STEPS TAKEN AFTER ASSESSMENT

Date submitted	Application type	Scope	Outcome

GAVISCON MINT FLAVOUR LIQUID
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SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT
Gaviscon Mint flavour liquid

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
Each 10 ml dose contains sodium alginate 500 mg, sodium hydrogen carbonate 267 mg and calcium carbonate 160 mg.
Excipients: methyl parahydroxybenzoate (E218) and propylparahydroxybenzoate (E216).
For full list of excipients, see Section 6.1.

3 PHARMACEUTICAL FORM
Oral suspension.

4 CLINICAL PARTICULARS
4.1 Therapeutic indications
Treatment of symptoms of gastro-oesophageal reflux such as acid regurgitation, heartburn and indigestion, for example, following meals or during pregnancy.

4.2 Posology and method of administration
For oral administration.
Adults and children 12 years and over: 10-20 ml after meals and at bedtime.
Children under 12 years: Should be given only on medical advice.
Elderly: No dose modifications necessary for this age group.

4.3 Contraindications
Hypersensitivity to any of the ingredients, including the esters if hydroxybenzoates (parabens).

4.4 Special warnings and precautions for use
Each 10 ml dose has a sodium content of 141 mg (6.2 mmol). This should be taken into account when a highly restricted salt diet is recommended. e.g. in some cases of congestive cardiac failure and renal impairment.

Each 10 ml dose contains 160 mg (1.6 mmol) of calcium carbonate. Care needs to be taken in treating patients with hypercalcaemia, nephrocalcinosis and recurrent calcium containing renal calculi.
There is a possibility of reduced efficacy in patients with very low levels of gastric acid.

If symptoms do not improve after seven days, the clinical situation should be reviewed.
Treatment of children younger than 12 years of age is not generally recommended, except on medical advice.

4.5 Interaction with other medicinal products and other forms of interaction
None known.

4.6 Pregnancy and lactation
Open controlled studies in 281 pregnant women did not demonstrate any significant adverse effects of Gaviscon on the course of pregnancy or on the health of the foetus/new-born child. Based on this and previous experience, this product may be used during pregnancy and lactation.

4.7 Effects on ability to drive and use machines
Not relevant.

4.8 Undesirable effects
Very rarely (≤1/10,000) patients may develop allergic manifestations such as urticaria or bronchospasm, anaphylactic or anaphylactoid reactions.

4.9 Overdose

In the event of overdosage symptomatic treatment should be given. The patient may notice abdominal distension.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic classification: A02BX. Other drugs for peptic ulcer and gastro-oesophageal reflux disease.

On ingestion the medicinal product reacts rapidly with gastric acid to form a raft of alginic acid gel having a near neutral pH and which floats on the stomach contents effectively impeding gastro-oesophageal reflux. In severe cases the raft itself may be refluxed into the oesophagus, in preference to the stomach contents, and exert a demulcent effect.

5.2 Pharmacokinetic properties

The mode of action of the medicinal product is physical and does not depend on absorption into the systemic circulation.

5.3 Preclinical safety data

No pre-clinical findings of any relevance to the prescriber have been reported.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Carbomer 974P, methyl (E218) and propyl (E216) parahydroxybenzoate, saccharin sodium, mint flavour no. 4, mint flavour no. 5, sodium hydroxide and purified water.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Two years.

6.4 Special precautions for storage

Do not store above 30°C. Do not refrigerate or freeze.

6.5 Nature and contents of container

Amber glass bottles with a polypropylene cap with a polyethylene tamper-evident band lined with expanded polyethylene wad and containing 100, 150, 200, 300, 500 or 600 ml.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

None required.

7 MARKETING AUTHORISATION HOLDER

Reckitt Benckiser Healthcare (UK) Limited,
Dansom Lane,
Hull, HU8 7DS,
United Kingdom.

8 MARKETING AUTHORISATION NUMBER(S)

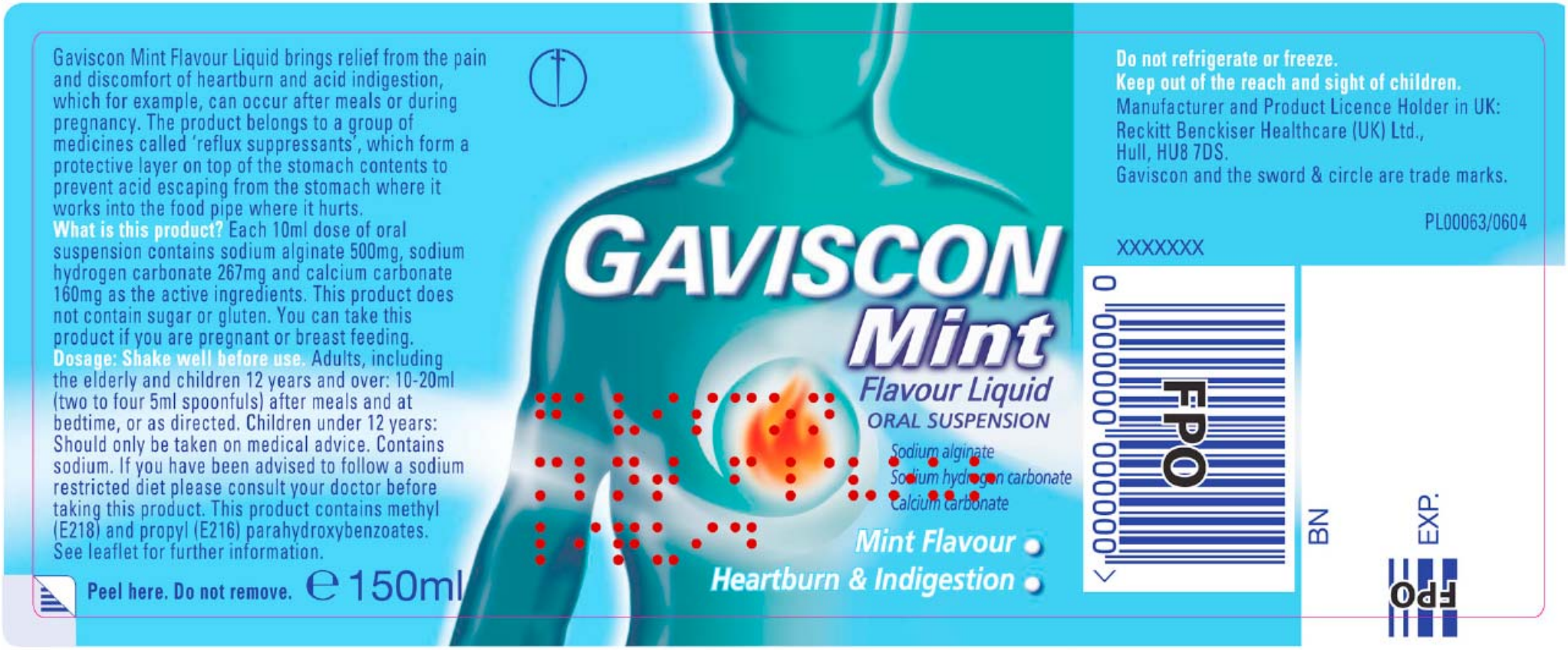
PL 00063/0604

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10/03/2009

10 DATE OF REVISION OF THE TEXT

10/03/2009


Gaviscon Mint Flavour Liquid brings relief from the pain and discomfort of heartburn and acid indigestion, which for example, can occur after meals or during pregnancy. The product belongs to a group of medicines called 'reflux suppressants', which form a protective layer on top of the stomach contents to prevent acid escaping from the stomach where it works into the food pipe where it hurts.
What is this product? Each 10ml dose of oral suspension contains sodium alginate 500mg, sodium hydrogen carbonate 267mg and calcium carbonate 160mg as the active ingredients. This product does not contain sugar or gluten. You can take this product if you are pregnant or breast feeding.
Dosage: Shake well before use. Adults, including the elderly and children 12 years and over: 10-20ml (two to four 5ml spoonfuls) after meals and at bedtime, or as directed. Children under 12 years: Should only be taken on medical advice. Contains sodium. If you have been advised to follow a sodium restricted diet please consult your doctor before taking this product. This product contains methyl (E218) and propyl (E216) parahydroxybenzoates. See leaflet for further information.
Peel here. Do not remove.
℮ 150ml
GAVISCON
Mint
Flavour Liquid
ORAL SUSPENSION
Sodium alginate
Sodium hydrogen carbonate
Calcium carbonate
Mint Flavour
Heartburn & Indigestion
Do not refrigerate or freeze.
Keep out of the reach and sight of children.
Manufacturer and Product Licence Holder in UK:
Reckitt Benckiser Healthcare (UK) Ltd.,
Hull, HU8 7DS.
Gaviscon and the sword & circle are trade marks.
PL00063/0604
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GAVISCON MINT FLAVOUR LIQUID

Sodium alginate
Sodium hydrogen carbonate
Calcium carbonate

PATIENT INFORMATION LEAFLET
PLEASE READ THIS LEAFLET CAREFULLY BEFORE YOU TAKE THIS MEDICINE.

IF YOU ARE NOT SURE ABOUT ANYTHING ASK YOUR PHARMACIST OR DOCTOR

What is Gaviscon Mint Flavour Liquid?
This product belongs to a group of medicines called "reflux suppressants". Reflux is a process in which the acid stomach juices flow back up into the food pipe. Unlike the stomach the lining of the food pipe is not resistant to acid so that when reflux occurs, it causes the pain and discomfort commonly known as heartburn. This product forms a protective layer that floats on top of the stomach contents. This layer prevents reflux and keeps the stomach contents away from the lining of the food pipe to relieve the symptoms of heartburn and acid indigestion.

What is Gaviscon Mint Flavour Liquid used for?
This product is used for the relief of heartburn and acid indigestion (also known as dyspepsia). Heartburn and acid indigestion are common and experienced by most people at some time. They may be felt as a burning sensation across the lower part of the chest, a pain spreading from the stomach towards the throat or regurgitation of a sour tasting liquid. Heartburn and acid indigestion often occur during pregnancy. Heartburn and acid indigestion can be made worse if you eat fatty or very spicy foods, drink too much alcohol, smoke, wear very tight clothing, are over weight or when you bend forward or lie down.

Before taking Gaviscon Mint Flavour Liquid:
Do not take if you know that you are allergic to any of the ingredients. (see further information for a full list)
You can take this product if you are pregnant or breast feeding. Each 10ml dose contains 4.6mmol of sodium.
If you have been advised to follow a low sodium (salt) diet please consult your doctor before taking this product.
This product contains methyl (E218) and propyl (E216) parahydroxybenzoates which may cause allergic reactions (possibly delayed).

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This treatment maybe less effective if you have decreased amounts of gastric acid produced in your stomach.

How to take Gaviscon Mint Flavour Liquid:
Adults, including the elderly and children 12 years and over: 10-20ml (two to four

5ml spoonfuls) after meals and at bedtime, or as directed.
Children under 12 years: Should only be taken on medical advice.
Shake well before use.

After taking Gaviscon Mint Flavour Liquid:
If you forget a dose it is not necessary to double the dose next time, just carry on taking as before. If you take too much of this product it is unlikely to cause you any harm. However, you may feel bloated. Consult your doctor or pharmacist if this does not go away.

Possible side effects:
Less than 1 in 10,000 chance of skin rash or difficulty in breathing due to an allergic reaction from the ingredients. Consult your doctor if you experience these or any other side-effects.

Storing your medicine:
Do not use this product after the expiry date (EXP: month/year) shown
• Keep out of the reach and sight of children • Do not refrigerate or freeze
• Check that the cap seal is unbroken before first using this product.

Further information:
Each 10 ml of oral suspension contains sodium alginate 500mg, sodium hydrogen carbonate 267mg and calcium carbonate 160mg as the active ingredients.The other ingredients are calcium carbonate, carbomer, methyl (E218) and propyl (E216) parahydroxybenzoates, sodium saccharin, sodium hydroxide, mint flavour and purified water.
This product does not contain sugar or gluten. Gaviscon Mint Flavour Liquid is available in bottles of 150ml and 300ml.

Manufacturer and Product Licence Holder in UK:
Reckitt Benckiser Healthcare (UK) Ltd., Hull, HU8 7DS.
Export Distributors:
Reckitt & Colman (Overseas) Ltd., Hull, HU8 7DS.
Gaviscon and the sword and circle are trade marks.
Text Revised: February 2009.

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