GAVISCON ADVANCE MINT CHEWABLE TABLETS
PL 00063/0613

UKPAR

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LAY SUMMARY

On 28 September 2010, the MHRA granted Reckitt Benckiser Healthcare (UK) Limited a Marketing Authorisation (licence) for the medicinal product Gaviscon Advance Mint Chewable Tablets (PL 00063/0613). This is a General Sale Licence (GSL) medicine.

Gaviscon Advance Mint Chewable Tablets belong to a group of medicines called “reflux suppressants”, which form a protective layer on top of the stomach contents to prevent stomach acid escaping from the stomach where it works into the food pipe causing pain and discomfort.

Gaviscon Advance Mint Chewable Tablets are used for the treatment of symptoms of gastro-oesophageal reflux, such as acid regurgitation, heartburn and indigestion, which may occur, for example, following meals or during pregnancy, and in patients with symptoms related to oesophagitis.

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

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INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the MHRA granted a Marketing Authorisation for the medicinal product Gaviscon Advance Mint Chewable Tablets (PL 00063/0613) to Reckitt Benckiser Healthcare (UK) Limited on the 28 September 2010. The product is available on a General Sales Licence (GSL).

Gaviscon Advance Mint Chewable Tablets contain the active ingredients sodium alginate and potassium bicarbonate, which belong to a group of medicines called other drugs for peptic ulcer and gastro-oesophageal reflux disease. This product is indicated for the treatment of symptoms of gastro-oesophageal reflux, such as acid regurgitation, heartburn and indigestion (related to reflux), for example, following meals, or during pregnancy, or in patients with symptoms related to reflux oesophagitis.

On ingestion, Gaviscon Advance Mint Chewable Tablets react rapidly with gastric acid to form a raft of alginic acid gel, which has a near neutral pH and which floats on the stomach contents effectively impeding gastrooesophageal reflux. In severe cases, the raft itself may be refluxed into the oesophagus, in preference to the stomach contents, and exert a demulcent effect.

This application was submitted as a simple abridged application according to Article 10c of Directive 2001/83/EC, cross-referring to Gaviscon Advance Tablets (PL 00063/0144) also held by Reckitt Benckiser Healthcare (UK) Limited, which was granted a Marketing Authorisation on 05 January 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.
PHARMACEUTICAL ASSESSMENT

LICENSE NO: PL 00063/0613
PROPRIETARY NAME: Gaviscon Advance Mint Chewable Tablets
COMPANY NAME: Reckitt Benckiser Healthcare (UK) Limited
E.C. ARTICLE: Article 10c of Directive 2001/83/EC
LEGAL STATUS: GSL

1 INTRODUCTION
This is a simple, informed consent application for Gaviscon Advance Mint chewable Tablets submitted under Article 10c of Directive 2001/83/EC. The application cross-refers to Gaviscon Advance Tablets (PL 00063/0144), approved on 05 October 2005 to the Marketing Authorisation Holder Reckitt Benckiser Healthcare (UK) Limited.

The current application is considered valid.

2 MARKETING AUTHORISATION APPLICATION (MAA)
2.1 Name(s)
The proposed name of the product is Gaviscon Advance Mint Chewable Tablets. The product has been named in-line with current requirements.

2.2 Strength, pharmaceutical form, route of administration, container and pack sizes
Gaviscon Advance Mint Chewable Tablets are presented as off-white to cream, circular, flat with bevelled edges tablets, and with the odour and flavour of peppermint.

Each tablet contains the active ingredients 500mg sodium alginate and 100mg potassium bicarbonate. The tablets are licensed for marketing in the following containers:

1) white, rigid, injection-moulded, polypropylene cylindrical containers with snap-bead neck finish in pack sizes of 20 or 60 tablets. Pack sizes are comprised of either three 20-tablet containers packed into a carton or one 60-tablet container. For some markets, the 60-tablet container will be packed into a carton.

2) unprinted, glass-clear, thermoformable laminate of unplasticised polyvinylchloride/polyethylene/polyvinylidene chloride/aluminium blisters packed into cartons. Each blister tray contains six individually sealed tablets with two or four blister trays in a carton (a total of 12 or 24 tablets per carton).

Not all pack sizes may be marketed. However, the Marketing Authorisation Holder has committed to submitting mock-ups of the packaging for any pack size to the relevant regulatory authorities for approval before marketing.

The proposed shelf life is 2 years, with the storage conditions ‘Do not store above 30°C. Store in the original package.’ The shelf-life and storage conditions are identical to those for the reference product and are satisfactory.

2.3 Legal status
The product is a General Sale Licence (GSL) medicine.
2.4 **Marketing authorisation holder/Contact Persons/Company**
The proposed Marketing Authorisation holder is Reckitt Benckiser Healthcare (UK) Limited, Dansom Lane, Hull, HU8 7DS, United Kingdom.

The Qualified Person (QP) responsible for pharmacovigilance is stated and their *Curriculum Vitae* (CV) is included.

2.5 **Manufacturers**
The proposed manufacturing sites are consistent with those registered for the reference product and evidence of Good Manufacturing Practice 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 is stated.

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

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

2.10 **TSE Compliance**
No materials of human or animal origin have been used in the manufacture of this product. This is consistent with the reference product.

2.11 **Bioequivalence**
No bioequivalence data are required to support this informed consent application, as the proposed product is manufactured to the same formula utilising the same process as the cross-reference product Gaviscon Advance Tablets (PL 00063/0144).

3 **EXPERT REPORT**
The applicant has included a detailed pharmaceutical expert report, written by an appropriately qualified person.

4 **PRODUCT NAME & APPEARANCE**
See 2.1 for details of the proposed product name. The appearance of the product is identical to that of 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)/LABELLING

The patient information leaflet has been prepared in-line with the details registered for the cross-reference product.

A 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, as amended. 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.

Carton and blister
The proposed artwork complies with the relevant statutory requirements. In-line with current legislation, the applicant has also included the name of the product in Braille on the outer packaging.

7. CONCLUSIONS
The data submitted with the application are acceptable. The grant of a Marketing Authorisation is recommended.
NON-ClinICAL ASSESSMENT

As this application is identical to the cross-reference product Gaviscon Advance Tablets (PL 00063/0144), no new non-clinical data have been supplied with this application and none are required. A non-clinical expert report has been written by a suitably qualified person and is satisfactory.
CLINICAL ASSESSMENT

As this application is identical to the cross-reference product Gaviscon Advance Tablets (PL 00063/0144), no new clinical data have been supplied with this application and none are required. A clinical expert report has been written by a suitably qualified person and is satisfactory.

The Marketing Authorisation Holder has provided adequate justification for not submitting a Risk Management Plan (RMP). As the application is for an identical version of an already authorised reference product, for which safety concerns requiring additional risk minimisation have not been identified, a risk minimisation system is not considered necessary. The reference product has been in use for many years and the safety profile of the active ingredient is well-established.

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

QUALITY
The data for this application are 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 an application of this type.

EFFICACY
This application is identical to the previously granted application for Gaviscon Advance Tablets (PL 00063/0144), granted to Reckitt Benckiser Healthcare (UK) Limited on 05 January 2005.

SAFETY
No new or unexpected safety concerns arise from this application.

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

Colour mock-ups of the labelling have been provided and are satisfactory. The approved labelling artwork complies with statutory requirements. The name of the product in Braille appears on the outer packaging.

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 reference product. Extensive clinical experience with sodium alginate and potassium bicarbonate is considered to have demonstrated the therapeutic value of the compounds. The benefit/risk is, therefore, considered to be positive.
**STEPS TAKEN FOR ASSESSMENT**

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<td>The MHRA received the marketing authorisation application on 20 August 2009</td>
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<td>Following standard checks and communication with the applicant the MHRA considered the application valid on 24 August 2009</td>
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<td>Following assessment of the application the MHRA requested further information on 28 August 2009.</td>
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<td>The applicant responded to the MHRA’s request, providing further information on 20 May 2010</td>
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<td>The application was determined on 28 September 2010</td>
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SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT
Gaviscon Advance Mint Chewable Tablets.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
Each tablet contains sodium alginate 500 mg and potassium bicarbonate 100 mg.
For excipients, see Section 6.1.

3 PHARMACEUTICAL FORM
Chewable tablet.

An off-white to cream, circular, flat with bevelled edges tablet with the odour and flavour of peppermint. Each tablet is imprinted with a "Sword and Circle” on one side and "GA500” on the reverse.

4 CLINICAL PARTICULARS
4.1 Therapeutic indications
Treatment of symptoms of gastro-oesophageal reflux such as acid regurgitation, heartburn and indigestion (related to reflux), for example, following meals, or during pregnancy, or in patients with symptoms related to reflux oesophagitis.

4.2 Posology and method of administration
For oral administration, after being thoroughly chewed.

Adults and children 12 years and over: One to two tablets 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
This medicinal product is contraindicated in patients with known or suspected hypersensitivity to the active substances or to any of the excipients.

4.4 Special warnings and precautions for use
The sodium content of a two-tablet dose is 103 mg (4.5 mmol) and a potassium content of 78 mg (2.0 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 or when taking drugs which can increase plasma potassium levels.

Each two-tablet dose contains 200 mg (2.0 mmol) of calcium carbonate. Care needs to be taken in treating patients with hypercalcaemia, nephrocalcinosis and recurrent calcium containing renal calculi.

Due to its aspartame content this product should not be given to patients with phenylketonuria. May cause central nervous system depression in the presence of renal insufficiency and should not be used in patients with renal failure. 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
An open controlled study in 146 pregnant women did not demonstrate any significant adverse effects of Gaviscon Advance on the course of pregnancy or on the health of the foetus/new-born child.
Based on this and previous experience, Gaviscon Advance Tablets may be used during pregnancy and lactation. Nevertheless, taking into account the presence of calcium carbonate it is recommended to limit the treatment duration as much as possible.

4.7 Effects on ability to drive and use machines
None.

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 13. Other drugs for peptic ulcer and gastro-oesophageal reflux disease.

On ingestion Gaviscon Advance Tablets react 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 gastrooesophageal 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 Gaviscon Advance Tablets 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
Mannitol
Calcium carbonate
Macrogol 20,000
Magnesium stearate
Aspartame
Mint flavour no. 3
Acesulfame potassium
Copovidone

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
Two years.

6.4 Special precautions for storage
Do not store above 30°C. Store in the original package.

6.5 Nature and contents of container
White, rigid, injection-moulded, polypropylene cylinder container with snap-bead neck finish.

Container containing 20 or 60 tablets. Pack sizes are comprised of either three 20-tablet containers packed into a carton or one 60-tablet container. For some markets the 60-tablet container will be packed into a carton.
Unprinted, glass-clear, thermoformable laminate of uPVC/PE/PVdC with aluminium foil lidding blisters packed into cartons.
Blister tray containing six individually sealed tablets. Two or four blister trays in a carton.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal
No special requirements.

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

8 MARKETING AUTHORISATION NUMBER(S)
PL 00063/0613.

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
28/09/2010

10 DATE OF REVISION OF THE TEXT
28/09/2010
PATIENT INFORMATION LEAFLET

GAVISCON ADVANCE MINT CHEWABLE TABLETS

Sodium alginate
Potassium bicarbonate

Please read this leaflet carefully before you take this medicine. If you are not sure about anything ask your pharmacist or doctor.

What are Gaviscon Advance Mint Chewable Tablets?
Gaviscon Advance Mint Chewable Tablets belong to a group of medicines called 'reflux suppressants', which form a protective layer on top of the stomach contents to prevent stomach acid escaping from the stomach where it works in the food pipe causing pain and discomfort.

What are Gaviscon Advance Mint Chewable Tablets used for?
Gaviscon Advance Mint Chewable Tablets are used for the treatment of symptoms of gastro-oesophageal reflux such as acid regurgitation, heartburn and indigestion, which may occur for example following meals or during pregnancy, and in patients with symptoms related to oesophagitis.

Before using Gaviscon Advance Mint Chewable Tablets:
- Do not take this product if:
  - You know you are allergic to any of the ingredients as very rarely difficulty in breathing and skin rashes have occurred (see Further-information for a full list)
- Take special care before treatment with Gaviscon Advance Mint Chewable Tablets:
  - This medicine contains sodium (4.5 mmol per two-tablet dose), potassium (2.0 mmol per two-tablet dose) and calcium (3.0 mmol per two-tablet dose).
  - If you have been advised to follow a diet restricted in either of these salts please consult your doctor before taking this product.
  - Please also talk to your doctor regarding these salt contents if you suffer or have suffered from significant kidney or heart disease, as certain salt could interfere with these diseases.

If you have phenylketonuria, note that this product is sweetened with aspartame, a source of phenylalanine.

Please consult your doctor if you know you have reduced amount of gastric acid in your stomach, as this product may be less effective.

Pregnancy and breastfeeding:
You can take this product if you are pregnant or breastfeeding. As with all medicines, the treatment duration should be limited as much as possible.

How to take Gaviscon Advance Mint Chewable Tablets:
For oral administration. Chew thoroughly before swallowing.

- Adult and children over 12 years: When symptoms occur take one to two tablets after meals and at bedtime.

- Children under 12 years: should only be taken on medical advice.

  - 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 you may feel bloated. It is unlikely to cause you any harm, but please consult your doctor or pharmacist.

After taking Gaviscon Advance Mint Chewable Tablets:
If symptoms persist after 7 days consult your doctor.

Possible side effects
Very rarely (less than 10,000) chance of an allergic reaction to the ingredients. Symptoms of this may include skin rash, difficulty in breathing, dizziness, or swelling of the face, lips, tongue or throat. If you experience these or any other side-effects stop taking the product and consult your doctor or pharmacist.

Storing your medicine:
Do not use after the expiry date (EXP month/year) shown on the pack.

KEEP OUT OF REACH AND SIGHT OF CHILDREN.
Do not store above 30°C.

Further information
Gaviscon Advance Mint Chewable Tablets are off-white to cream, circular, flat with bevelled edges tablets with the odour and flavour of peppermint. Each tablet contains sodium alginate 500 mg and potassium bicarbonate 100 mg as the active ingredients. The other ingredients are mannitol (E421), calcium carbonate, macrogol 20,000, magnesium stearate, aspartame (E951), mint flavour,acesulfame potassium, copovidone.

These tablets do not contain sugar or gluten. Gaviscon Advance Mint Chewable Tablets are available in pack sizes 12’s & 24’s

Manufacturer:
Reckitt Benckiser Healthcare (UK) Limited, Dansen Lane, Hull, HU1 7DS.

PL Holder: Reckitt Benckiser Healthcare (UK) Limited, 103-105 Bath Road, Slough, Berkshire, SL1 3UH

Gaviscon and are trade marks.
Text revised: June 2010
Label/leaflet:

Gaviscon Advance Mint Chewable Tablets

Dispensing only

Gaviscon Advance Mint Chewable Tablets provide relief from the pain and discomfort of acid regurgitation, indigestion and heartburn, which can occur after meals and during pregnancy. They work by forming a protective layer on top of the stomach so preventing stomach acid escaping into the food pipe.

Before taking this product Do not take if you have a condition called phenylketonuria. Consult your doctor before taking if you suffer from heart or kidney disease or are taking diuretics ('water tablets').

Sodium alginate
Potassium bicarbonate

You can take this product if you are pregnant or breastfeeding.

Dose: For oral use only. Adults including the elderly and children 12 years and over: Take 1-2 tablets after meals and at bedtime, or as directed. Chew thoroughly before swallowing. Children under 12 years: Should only be taken on medical advice. Take for the shortest time possible. If symptoms persist for longer than 7 days, consult your doctor. KEEP OUT OF THE REACH AND SIGHT OF CHILDREN. See leaflet for further information.

Manufacturer and Product Licence Holder in UK: Reckitt Benckiser Healthcare (UK) Limited, Danson Lane, Hull, HU8 7DS, UK.

UK Distributors: Forum Health Products Ltd.
2. Before taking Gaviscon Advance Mint Chewable Tablets
Do not take Gaviscon Advance Mint Chewable Tablets if you
• are allergic to any of the ingredients listed in Section 6
• have a condition called phenylketonuria (as this product is sweetened
  with aspartame, a source of phenylalanine which is harmful to patients
  with phenylketonuria).
Please consult your doctor before taking Gaviscon Advance Mint Chewable Tablets if you
• are on a potassium, sodium or calcium restricted diet, as each two tablet
  dose contains small amounts of sodium (4.6mmol per 10ml), potassium
  (2.0mmol per 10ml) and calcium (2.0mmol per 10ml)
• suffer from heart disease or kidney disease
• are taking diuretics (water tablets) for high blood pressure as the salt
  content of these tablets can affect the above diseases and the effect of
  diuretics.
Please note that if your stomach produces reduced amounts of acid, this
product may be less effective.

Pregnancy and breastfeeding
You can take this product if you are pregnant or breastfeeding.
3. How to take Gaviscon Advance Mint Chewable Tablets
For oral use only.
Adults including the elderly and children 12 years and over
Take 1-2 tablets after meals and at bedtime, or as directed.
Chew thoroughly before swallowing.
Children under 12 years
Should only be taken on medical advice.

After taking this product
• If you forget a dose, do not double the dose next time, just skip it and carry on as before.
• If you take too much, you may feel bloated. It is unlikely to cause you harm, but please consult your doctor or pharmacist.
• As with all medicines, treatment should be as short as possible.
• If symptoms persist for longer than 7 days, consult your doctor.

4. Possible side effects
Side effects are very rare (less than 1 in 10,000 users) and include rash, difficulty breathing, dizziness due to an allergic reaction to the ingredients.
If you experience these or any other effects not listed, stop taking the tablets and consult your doctor immediately.

5. How to store Gaviscon Advance Mint Chewable Tablets
KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.
Store in the original package, Do not store above 25°C.
Do not use after the expiry date shown after 'EXP' on the pack.
Medicines should not be disposed of via wastewater 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
Each tablet contains 500mg sodium alginate and 100mg potassium bicarbonate, as the active ingredients. The other ingredients are mannitol (E421), calcium carbonate, macrogol 20,000, copovidone, magnesium stearate, aspartame (951), acesulfame potassium and mint flavour.
Manufacturer and Product License Holder: Reckitt Benckiser Healthcare (UK) Ltd, Damson Lane, Hull UK, HU8 7DS.
Gaviscon is a Trademark.
Leaflet last revised March 2010.
Carton:

Gaviscon Advance Mint Chewable Tablets provide relief from the pain and discomfort of acid reflux, indigestion and heartburn, which for example can occur after meals and during pregnancy. They are a type of medicine called reflux suppressants, which work by forming a protective layer on top of the stomach contents so preventing stomach acid escaping into the food pipe.

What are these tablets? Each chewable tablet contains 500 mg sodium alginate and 100 mg potassium bicarbonate as the active ingredients. The tablets do not contain sugar or gluten. You can take this product if you are pregnant or breastfeeding.

Dosage: For oral administration. Chew thoroughly before swallowing.

Adults including the elderly and children 12 years and over: When symptoms occur take 1-2 tablets after meals and at bedtime. Children under 12 years: should only be taken on medical advice. If symptoms persist after 7 days consult your doctor. This medicine contains sodium, potassium and calcium. If you have been advised to follow a diet restricted in one of these salts please consult your doctor before taking this product. If you have phenylketonuria, note that this product is sweetened with aspartame (E951), a source of phenylalanine.

See enclosed leaflet for further information.

Keep out of the sight and reach of children.

Do not store above 30°C.