WIND-EZE GEL CAPS
(Simeticone)
PL 00036/0305

UKPAR

TABLE OF CONTENTS

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LAY SUMMARY

The MHRA granted Stafford-Miller Limited a Marketing Authorisation (licence) for the medicinal product Wind-eze Gel Caps on 03 August 2010. This is a General Sales List (GSL) medicine for the treatment of the symptoms of stomach pain and bloating due the presence of trapped wind.

Wind-eze Gel Caps contains the active ingredient simeticone, an anti-flatulence medicine that works by gently dispersing the tiny bubbles.

This is an abridged application submitted under Article 10c (formerly Article 10.1(a)(i)) of EC Directive 2001/83, as amended. This application cross-refers to Wind-eze Gel Caps (PL 00036/0073), also licensed to Stafford-Miller Limited on 16th June 1997.

No new or unexpected safety concerns arose from this simple application and it was, therefore, judged that the benefits of taking Wind-eze Gel Caps outweigh the risks; hence a Marketing Authorisation has been granted.

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SCIENTIFIC DISCUSSION

TABLE OF CONTENTS

INTRODUCTION

The UK granted a Marketing Authorisation for the medicinal product Wind-eze Gel Caps (PL 00036/0305) to Stafford-Miller Limited on 3 August 2010. The product is available as a General Sales List (GSL) medicine and is used for the symptomatic relief of flatulence, wind pains, bloating, abdominal distension and other symptoms associated with gastrointestinal gas.

The application was submitted as an abridged application according to Article 10c (formerly Article 10.1(a)(i)) of Directive 2001/83/EC. This application cross-refers to Wind-eze Gel Caps (PL 00036/0073), first approved on 16 June 1997 to the same Marketing Authorisation Holder.

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.

The product contains the active ingredient simeticone, which is an anti-flatulent. Simeticone is physiologically inert and has no pharmacological effect. It acts by changing the surface tension of gas bubbles, causing them to coalesce.

PHARMACEUTICAL ASSESSMENT

LICENCE NO: PL 00036/0305
PROPRIETARY NAME: Wind-eze Gel Caps
ACTIVE(S): Simeticone
COMPANY NAME: Stafford-Miller 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 Wind-eze Gel Caps submitted under Article 10c (formerly Article 10.1(a)(i)) of Directive 2001/83/EC. The proposed Marketing Authorisation Holder is Stafford-Miller Limited, 980 Great West Road, Brentford, Middlesex, TW8 9GS, UK (trading as GlaxoSmithKline Consumer Healthcare, Brentford, TW8 9GS, UK).

The application cross-refers to Wind-eze Gel Caps (PL 00036/0073), which was approved on 16 June 1997 to Stafford-Miller Limited. The current application is considered valid.

2. MARKETING AUTHORISATION APPLICATION FORM

2.1 Name(s)

The proposed name of the product is Wind-eze Gel Caps. The justification provided for the use of the same name as that of the reference product is acceptable.

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

Each soft capsule contains 125mg simeticone (activated dimeticone). The product is packaged in polyvinylchloride/polyvinylchloride/aluminium blister packs. Wind-eze Caps are available in pack sizes of 10, 20, 30, 50 and 60 capsules. Not all pack sizes may be marketed. However, the marketing authorisation holder has committed to submitted mock-ups of any pack size for approval before marketing.

The proposed shelf-life (3 years) and storage conditions (Do not store above 25°C) 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 List (GSL) medicine.

2.4 Marketing Authorisation Holder/Contact Persons/Company

Stafford-Miller Limited, 980 Great West Road, Brentford, Middlesex, TW8 9GS, UK (trading as GlaxoSmithKline Consumer Healthcare Brentford, TW8 9GS, UK).

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 compliance with Good Manufacturing Practice (GMP) 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 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
With the exception of gelatin, none of the excipients contain materials of animal or human origin. Certificates of Suitability from the European Directorate for the Quality of Medicines have been provided for the suppliers of gelatin, showing that it complies with current guidelines concerning the minimising of TSE/BSE transmission.

2.11 Bioequivalence
No bioequivalence data are required to support this application, as the proposed product is manufactured to the same formula utilising the same process as the reference product Wind-eze Gel Caps (PL 00036/0073).

3. EXPERT REPORTS
The applicant cross-refers to the data for Wind-eze Gel Caps (PL 00036/0073) to which it claims identicality. This is acceptable.

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 of Product Characteristics is consistent with the details registered for the cross-reference product.

6. PATIENT INFORMATION LEAFLET (PIL)/CARTON
PIL
The patient information leaflet (label-leaflet) has been prepared in-line with the details registered for the cross-reference product and is incorporated into the product information provided for the carton.

The applicant has previously submitted results of consultations with target patient groups ("user testing"), in accordance with Article 59 of Council Directive 2001/83/EC for the reference product Wind-eze Gel Caps (PL 00036/0073). The results indicate that the label-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.

As the label-leaflet for Wind-eze Gel Caps (PL 00036/0073) and this product is considered the same, no further user testing of the label-leaflet for this product is necessary.

Carton and blister

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

7. CONCLUSION

The data submitted with the application are acceptable. A Marketing Authorisation should be granted.

NON-CLINICAL ASSESSMENT

As this is an abridged simple application, no new non-clinical data have been supplied and none are required.

The Marketing Authorisation Holder has provided adequate justification for not submitting an Environment Risk Assessment (ERA). As the application is for an identical version of an already authorised reference product, it is not expected that the environmental exposure to simeticone will increase following the marketing approval of the proposed product.

CLINICAL ASSESSMENT

As this is an abridged simple application, no new clinical data have been supplied and none are required.

OVERALL CONCLUSION AND BENEFIT/RISK ASSESSMENT QUALITY

QUALITY

The data for this application are consistent with that 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 a previously granted application for Wind-eze Gel Caps (PL 00036/0073). 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.

BENEFIT/RISK 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 simeticone is considered to have demonstrated the therapeutic value of the compound. The benefit/risk is, therefore, considered to be positive.

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STEPS TAKEN FOR ASSESSMENT

1 **The MHRA received the marketing authorisation application on 26 February 2008.**

2 **Following standard checks and communication with the applicant the MHRA considered the application valid on 13 March 2008.**

3 **Following assessment of the application the MHRA requested further information relating to the dossier on 12 May 2008 and 23 April 2010.**

4 **The applicant responded to the MHRA's requests, providing further information on 08 April 2010 and 26 July 2010.**

5 **The application was determined on 03 August 2010.**

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Wind-eze Gel Caps

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each soft capsule contains: 125mg Simeticone (activated dimeticone)

For excipients see 6.1

3 PHARMACEUTICAL FORM

Capsule, soft.

The capsules are oval gelatin capsules with a white to off white opaque gelatin shell.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

The symptomatic relief of flatulence, wind pains, bloating, abdominal distension and other symptoms associated with gastrointestinal gas.

4.2 Posology and method of administration

For oral administration:

Adults, children (12 years and above) and elderly:

One capsule to be taken three or four times daily or as required for relief, after meals and upon retiring.

Not recommended for children under 12 years of age.

4.3 Contraindications

The product should not be used in patients with known hypersensitivity to simeticone or to any excipients of the medicinal product.

4.4 Special warnings and precautions for use

If symptoms persist or worsen, the patient should consult their medical practitioner for further investigation.

This medicinal product contains glycerol. Harmful in high doses. Can cause headache and can cause stomach upset and diarrhoea.

4.5 Interaction with other medicinal products and other forms of interaction

Although no studies have been presented, the concomitant use of this drug and mineral oil (paraffin) based laxatives is not recommended since mixing of these two will diminish the efficacy.

4.6 Pregnancy and lactation

As thus far known, this drug can be used during pregnancy in compliance with the prescription, without any further restriction.

4.7 **Effects on ability to drive and use machines**

None known.

4.8 Undesirable effects

Minor adverse effects: nausea and constipation. Rarely hypersensitivity reactions such as rash, pruritis, facial oedema, tongue oedema, respiratory difficulty.

4.9 Overdose

In the unlikely event of deliberate overdosage, treat symptoms on appearance. There are no special procedures recommended.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Simeticone is an anti-flatulent with ATC code A03AX13. Physiologically simeticone is extremely inert, and therefore it will not be pharmacologically active. It acts by changing the surface tension of gas bubbles, causing them to coalesce.

5.2 Pharmacokinetic properties

Simeticone is not absorbed following oral administration.

5.3 Preclinical safety data

Simeticone is physiologically inert and considered to be non-toxic. Preclinical data reveal no hazard for humans.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Capsule shell:
Gelatin
Glycerol
Titanium Dioxide (E171)
Purified Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Blister packs of construction PVDC/PVC and aluminium foil with heat sealing coat.

Pack sizes: 10, 20, 30, 50 and 60.

Not all pack sizes may be marketed

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Stafford-Miller Limited
980 Great West Road
Brentford
Middlesex
TW8 9GS
UK

Trading as :
GlaxoSmithKline Consumer Healthcare
Brentford, TW8 9GS. UK

8 MARKETING AUTHORISATION NUMBER(S)

PL 00036/0305

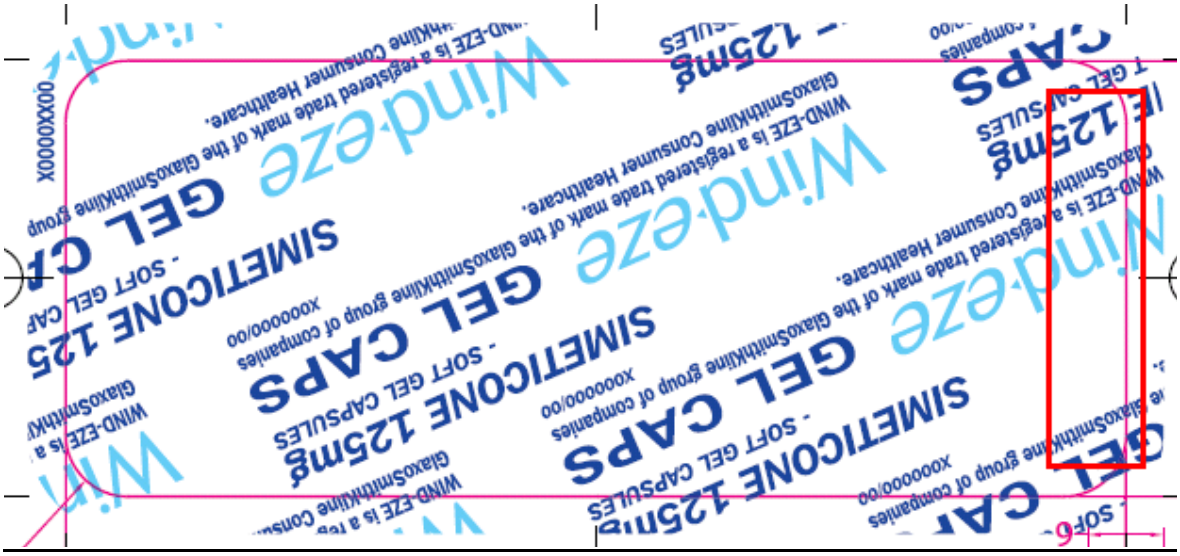
9 DATE OF FIRST AUTHORISATION/RENEWAL OF THEAUTHORISATION

03/08/2010

10 DATE OF REVISION OF THE TEXT

03/08/2010

LEAFLET/LABELLING


Wind-eze
GEL CAPS
SIMETICONE 125mg
- SOFT GEL CAPSULES
WIND-EZE is a registered trade mark of the GlaxoSmithKline group of companies
GlaxoSmithKline Consumer Healthcare.
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