AMOXICILLIN 250MG CAPSULES, HARD
AMOXICILLIN 500MG CAPSULES, HARD

UKPAR

TABLE OF CONTENTS

Lay Summary ............................................. Page 2
Scientific discussion ..................................... Page 3
Steps taken for assessment ............................. Page 12
Steps taken after authorisation – summary ............ Page 13
Summary of Product Characteristics
Product Information Leaflet
Labelling
AMOXICILLIN 250MG CAPSULES, HARD
AMOXICILLIN 500MG CAPSULES, HARD

LAY SUMMARY

On 10 August 2012, the MHRA granted Morningside Healthcare Limited Marketing Authorisations (licences) for the medicinal products Amoxicillin 250mg and 500mg Capsules, Hard (PL 20117/0214-5). These are prescription-only medicines (POM) used to treat a wide range of bacterial infections, which may include those affecting the:

- Chest (bronchitis or pneumonia)
- Tonsils (tonsillitis)
- Pharynx (pharyngitis)
- Ears (otitis media)
- Sinuses (sinusitis)
- Kidneys, bladder or the urethra (cystitis, urethritis, pyelonephritis)
- Abdomen (gastro-intestinal infections)
- Heart (endocarditis)

Amoxicillin 250mg and 500mg Capsules, Hard contains the active substance amoxicillin (as amoxicillin trihydrate), which is one of a group of medicines called “penicillins”. These medicines are also known as “antibiotics” and they work by killing the bacteria that cause infections.

No new or unexpected safety concerns arose from these applications and it was, therefore, judged that the benefits of taking Amoxicillin 250mg and 500mg Capsules, Hard outweigh the risks, hence Marketing Authorisations have been granted.
AMOXICILLIN 250MG CAPSULES, HARD
AMOXICILLIN 500MG CAPSULES, HARD

SCIENTIFIC DISCUSSION

TABLE OF CONTENTS

Introduction Page 4
Pharmaceutical assessment Page 5
Preclinical assessment Page 7
Clinical assessment (including statistical assessment) Page 8
Overall conclusions and risk benefit assessment Page 11
INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the UK granted marketing authorisations for the medicinal products Amoxicillin 250mg and 500mg Capsules, Hard (PL 20117/0214-5) on 10 August 2012 to Morningside Healthcare Limited.

These are applications for two strengths of Amoxicillin Capsules, Hard, submitted as abridged simple applications according to Article 10c of Directive 2001/83/EC, cross-refering to Amoxicillin 250 and 500mg Capsules (PL 20117/0030-1), which were originally granted licences to Morningside Healthcare Limited in March 2008.

The products contain the active ingredient amoxicillin, an aminopenicillin that is used principally for the treatment of infections caused by susceptible gram-negative bacteria (e.g., *Haemophilus influenzae*, *Escherichia coli*, *Proteus mirabilis*, *Salmonella*). Amoxicillin is also used for the treatment of infections caused by susceptible gram-positive bacteria (e.g., *Streptococcus pneumoniae*, enterococci, nonpenicillinase-producing staphylococci, *Listeria*). However, like other aminopenicillins, amoxicillin generally should not be used for the treatment of streptococcal or staphylococcal infections (when a natural penicillin would be effective).

Amoxicillin is indicated for the treatment of the following bacterial infections when caused by amoxicillin-sensitive gram-positive and gram-negative pathogens:

- Infections of the upper respiratory tract, including infections of the ears, nose and throat: Acute otitis media, acute sinusitis and bacterial pharyngitis.
- Infections of the kidneys and the genito-urinary tract: Cystitis, pyelonephritis.
- Infections of the gastrointestinal tract: It may be necessary to use combination therapy when treating infections caused by anaerobic organisms.
- Endocarditis: Amoxicillin may be used for the prevention of bacteraemia, associated with procedures such as dental extraction, in patients at risk of developing bacterial endocarditis. Amoxicillin may also be used for the treatment of endocarditis as an extension of parenteral therapy.
PHARMACEUTICAL ASSESSMENT

LICENCE NO: PL 20117/0214-5
PROPRIETARY NAME: Amoxicillin 250mg and 500mg Capsules, Hard
ACTIVE(S): Amoxicillin trihydrate
COMPANY NAME: Morningside Healthcare Limited
LEGAL STATUS: POM

1. INTRODUCTION
These are simple, piggyback applications for Amoxicillin 250mg and 500mg Capsules, Hard submitted under Article 10c (formerly Article 10.1(a)(i)) of Directive 2001/83/EC. The proposed MA holder is Morningside Healthcare Limited, 115 Narborough Road, Leicester, LE3 0PA, United Kingdom.

The applications cross-refer to Amoxicillin 250 and 500mg Capsules (PL 20117/0030-1), which were originally granted licences to Morningside Healthcare Limited in March 2008.

The current applications are considered valid.

2. MARKETING AUTHORISATION APPLICATION FORM
2.1 NAME(S)
The proposed names of the products are Amoxicillin 250mg Capsules, Hard, and Amoxicillin 500mg Capsules, Hard. The products have been named in line with current requirements.

2.2 Strength, pharmaceutical form, route of administration, container and pack sizes
Each filled capsule contains 250mg or 500mg amoxicillin. They are to be packed in aluminium/polyvinylchloride blister packs in pack sizes of 21 capsules. Not all pack sizes may be marketed, but the marketing authorisation holder has committed to submitting all labelling mock-ups to the licensing authorities for approval before marketing any pack size of the product.

The proposed shelf-life (36 months) and storage conditions (Store below 30°C) are consistent with the details registered for the cross-reference products.

2.3 Legal status
On approval, the products will be available as prescription-only medicines (POM).

2.4 Marketing authorisation holder/Contact Persons/Company
Morningside Healthcare Limited, 115 Narborough Road, Leicester, LE3 0PA, 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 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 products and the maximum batch sizes are stated.

2.8 Finished product/shelf-life specification
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 specification is consistent with the details registered for the cross-reference products.

2.10 TSE Compliance
With the exception of gelatin, no materials of animal or human origin are included in these products. Suitable certificates have been provided to show that the gelatin is sourced under conditions in line with current regulations concerning the minimising of BSE/TSE. This is consistent with the cross-reference products.

3. EXPERT REPORTS
The applicant has included detailed expert reports in Module 2 of the applications. 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 names. The appearance of the products is identical to the cross-reference products.

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

6. PATIENT INFORMATION LEAFLET/CARTON
PIL
The patient information leaflet has been prepared in-line with the details registered for the cross-reference products.

Carton and blister
The proposed artwork is comparable to the artwork registered for the cross-reference products 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. CONCLUSIONS
The data submitted with the applications are acceptable. From a quality perspective, Marketing Authorisations should be granted.

NON-CLINICAL ASSESSMENT
No new non-clinical data have been supplied with these applications and none are required for applications of this type.

CLINICAL ASSESSMENT
No new clinical data have been supplied with these applications and none are required for applications of this type.

OVERALL CONCLUSION AND RISK BENEFIT ASSESSMENT

QUALITY
The important quality characteristics of Amoxicillin 250mg and 500mg Capsules Hard are well-defined and controlled. The specifications and batch analytical results indicate consistency from batch to batch. There are no outstanding quality issues that would have a negative impact on the benefit/risk balance.

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

CLINICAL PHARMACOLOGY/EFFICACY
No new clinical pharmacology/efficacy data have been submitted with these applications and none are required.

SAFETY
No new safety data have been submitted with these applications and none are required.

No new or unexpected safety concerns arise from these applications.

The SPC, PIL and labelling are satisfactory.

RISK-BENEFIT ASSESSMENT
The quality of the product is acceptable and no new preclinical or clinical safety concerns have been identified. Extensive clinical experience with amoxicillin is considered to have demonstrated the therapeutic value of the compound. The risk benefit is, therefore, considered to be positive.
## STEPS TAKEN FOR ASSESMENT

<table>
<thead>
<tr>
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<th>Description</th>
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<tbody>
<tr>
<td>1</td>
<td>The MHRA received the marketing authorisation applications on 14 September 2011</td>
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<tr>
<td>2</td>
<td>Following standard checks and communication with the applicant the MHRA considered the applications valid on 12 October 2011</td>
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<td>3</td>
<td>Following assessment of the applications the MHRA requested further information relating to the dossiers on 9 December 2011 and 6 March 2012.</td>
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<td>4</td>
<td>The applicant responded to the MHRA’s requests, providing further information on 13 January 2012 and 8 June 2012.</td>
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<td>5</td>
<td>The applications were determined on 10 August 2012</td>
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AMOXICILLIN 250MG CAPSULES, HARD
AMOXICILLIN 500MG CAPSULES, HARD

STEPS TAKEN AFTER AUTHORISATION - SUMMARY

<table>
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<tr>
<th>Date submitted</th>
<th>Application type</th>
<th>Scope</th>
<th>Outcome</th>
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Summary of Product Characteristics and Patient Information Leaflet
The current approved UK versions of the Summaries of Product Characteristics (SmPCs) and Patient Information Leaflets (PILs) for these products is available on the MHRA website.
Labelling

MORNINGSIDE HEALTHCARE LIMITED
COMMON TECHNICAL DOCUMENT
MODULE 1 ADMINISTRATIVE INFORMATION
MODULE 1.3, PRESCRIBING INFORMATION

PARTICULARS TO APPEAR ON THE <OUTER PACKAGING> <AND> <THE IMMEDIATE PACKAGING>
{NATURE/TYPE}

1. NAME OF THE MEDICINAL PRODUCT

Amoxicillin 250mg Capsules
Amoxicillin

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each capsule contains Amoxicillin 250 mg (as tihydrate)

3. LIST OF EXCIPIENTS

Also contains sunset yellow E110, carmoisine E122, methyl parahydroxybenzoate and methyl parahydroxybenzoate.
See packaging leaflet for further information

4. PHARMACEUTICAL FORM AND CONTENTS

Capsules

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the reach and sight of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY
MORNINGSIDE HEALTHCARE LIMITED
COMMON TECHNICAL DOCUMENT
MODULE 1 ADMINISTRATIVE INFORMATION
MODULE 1.3, PRESCRIBING INFORMATION

8. EXPIRY DATE

EXP:
Exp:

9. SPECIAL STORAGE CONDITIONS

Store below 30°C

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Morningside Healthcare Ltd
115 Narborough Road
Leicester. LE3 0PA
United Kingdom

12. MARKETING AUTHORISATION NUMBER(S)

PL 20117/0214

13. BATCH NUMBER

BN:
Batch:
Lot:

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.
Amoxicillin 250mg Capsules
MORNINGSIDE HEALTHCARE LIMITED
COMMON TECHNICAL DOCUMENT
MODULE 1 ADMINISTRATIVE INFORMATION
MODULE 1.3, PRESCRIBING INFORMATION

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Blister/Label

1. NAME OF THE MEDICINAL PRODUCT

Amoxicillin 250mg Capsules
Amoxicillin

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Morningside Healthcare Ltd

3. EXPIRY DATE

EXP:
Exp:

4. BATCH NUMBER

BN:
Batch:
Lot:

5. OTHER


MORNINGSIDE HEALTHCARE LIMITED
COMMON TECHNICAL DOCUMENT
MODULE 1 ADMINISTRATIVE INFORMATION
MODULE 1.3, PRESCRIBING INFORMATION

PARTICULARS TO APPEAR ON THE <OUTER PACKAGING> <AND> <THE IMMEDIATE PACKAGING>
{NATURE/TYPE}

1. NAME OF THE MEDICINAL PRODUCT

Amoxicillin 500 mg Capsules
Amoxicillin

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each capsule contains Amoxicillin 500 mg (as tihydrate)

3. LIST OF EXCIPIENTS

Also contains sunset yellow E110, carmoisine E122, methyl parahydroxybenzoate and
methyl parahydroxybenzoate.
See packaging leaflet for further information

4. PHARMACEUTICAL FORM AND CONTENTS

Capsules
21

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the reach and sight of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY
MORNINGSIDE HEALTHCARE LIMITED
COMMON TECHNICAL DOCUMENT
MODULE 1 ADMINISTRATIVE INFORMATION
MODULE 1.3, PRESCRIBING INFORMATION

8. EXPIRY DATE

EXP:
Exp:

9. SPECIAL STORAGE CONDITIONS

Store below 30°C

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

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Morningside Healthcare Ltd
115 Narborough Road
Leicester, LE3 0PA
United Kingdom

12. MARKETING AUTHORISATION NUMBER(S)

PL 20117/0214

13. BATCH NUMBER

BN:
Batch:
Lot:

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.
15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Amoxicillin 500 mg Capsules
MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Blisters/Label

1. **NAME OF THE MEDICINAL PRODUCT**

Amoxicillin 500 mg Capsules
Amoxicillin

2. **NAME OF THE MARKETING AUTHORISATION HOLDER**

Morningside Healthcare Ltd

3. **EXPIRY DATE**

EXP:
Exp:

4. **BATCH NUMBER**

BN:
Batch:
Lot:

5. **OTHER**
