Oxytetracycline 250 mg Tablets

PL 20416/0221

UKPAR

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Safeguarding public health
Oxytetracycline 250 mg Tablets

PL 20416/0221

LAY SUMMARY

On 22nd August 2012, the MHRA granted a Marketing Authorisation (licence) for the medicinal product Oxytetracycline 250 mg Tablets (PL 20416/0221). This medicine is only available on prescription from your doctor.

These tablets contain the active ingredient, oxytetracycline. Oxytetracycline belongs to a group of medicines called broad spectrum antibiotics. This means that it is active against a large number of bacteria which cause infections.

Oxytetracycline tablets are used to treat a wide range of infections caused by bacteria. They are also used for preventing and treating chronic bronchitis, severe acne, urinary tract (bladder and kidney) infections and venereal diseases such as syphilis and gonorrhoea.

No new or unexpected safety concerns arose from this application and it was, therefore, judged that the benefits of taking Oxytetracycline 250 mg Tablets outweigh the risks; hence a Marketing Authorisation has been granted.
Oxytetracycline 250 mg Tablets

PL 20416/0221

SCIENTIFIC DISCUSSION

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INTRODUCTION

The Medicines and Healthcare Products Regulatory Agency (MHRA) granted a Marketing Authorisation (licence) for the medicinal product Oxytetracycline 250 mg Tablets (PL 20416/0221) to Crescent Pharma Ltd on the 22nd August 2012.

This prescription only medicine (POM) is used for the treatment of infections due to Chlamydia, Brucella, Mycoplasma, Rickettsia, and other sensitive organisms. The product can also be used for prophylaxis and treatment of chronic bronchitis, non-gonococcal urethritis, gonorrhoea, syphilis, other urinary tract infections and severe acne vulgaris.

This application was submitted as an abridged application according to Article 10c of Directive 2001/83/EC as amended, cross-referring to Oxytetracycline tablets BP 250 mg (PL 17496/0003), first approved to Dalkeith Laboratories Ltd on 16th May 2000.

No new data were submitted nor were they necessary for this simple application, as the data are identical to those of the previously granted cross-reference product. As the cross-reference product was granted prior to the introduction of current legislation, no Public Assessment Report (PAR) was generated.

Details of a pharmacovigilance system have been provided with this application and are satisfactory. A suitable justification for non-submission of the Risk Management Plan has been provided.

No Environmental Risk Assessment (ERA) has been undertaken, as this is not considered necessary. This product is essentially similar and the therapeutic indications and posology of the finished product are the same as those for the already licensed product. The applicant’s justification for the absence of an ERA is satisfactory.
PHARMACEUTICAL ASSESSMENT

LICENCE NO: PL 20416/0221
PROPRIETARY NAME: Oxytetracycline 250 mg Tablets
COMPANY NAME: Crescent Pharma Ltd
E.C. ARTICLE: Article 10c of Directive 2001/83/EC
LEGAL STATUS: POM

1 INTRODUCTION
This is an informed consent application for Oxytetracycline 250 mg Tablets, submitted under Article 10c of Directive 2001/83/EC as amended. This product is cross-referring to Oxytetracycline tablets BP 250mg, first approved for Dalkeith Laboratories Ltd on 16th May 2000 (PL 17496/0003). The current application is considered valid.

2 MARKETING AUTHORISATION APPLICATION (MAA)
2.1 Name(s)
The proposed name of the product is Oxytetracycline 250 mg Tablets. The product has been named in line with current requirements.

2.2 Strength, pharmaceutical form, route of administration, container and pack sizes
The product is a tablet for oral use and contains 250 mg of the active ingredient oxytetracycline dihydrate.

The tablets are packed either in blister strips comprising polyvinylchloride/Aluminium foil enclosed in an outer carton with a pack size of 28 tablets.

Or in

High-density polyethylene (HDPE) bottles with Low-density polyethylene (LDPE) cap, available in a pack of 1000 tablets.

Specifications and Certificates of Analysis for all packaging components used have been provided and are satisfactory. The packaging and pack sizes are the same as those of the reference product.

The proposed shelf life is 3 years with storage conditions “Do not store above 25°C” and “Keep the container tightly closed” for the HDPE tablet containers and “Do not store above 25°C” and “Store in the original package” for the blister. The shelf-life and storage conditions are identical to those for the cross-reference product and are satisfactory.

2.3 Legal status
This product is Prescription Only Medicine (POM).
2.4 Marketing authorisation holder/Contact Persons/Company
The proposed Marketing Authorisation Holder is Crescent Pharma Ltd, Units 3 & 4, Quidhampton Business Units, Polhampton Lane, Overton, Hampshire, RG25 3ED, United Kingdom

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 compositions are 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 full scale batch size is stated.

2.8 Finished product specifications
The proposed finished product specifications, at release and shelf-life, are in line with the details registered for the cross-reference product.

2.9 Drug substance specification
The proposed drug substance specification conforms to the current European Pharmacopoeia monograph for oxytetracycline dihydrate and is in-line with that 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.

Confirmation has been provided that the magnesium stearate used in the tablet is of vegetable origin. The milk used in the product of the lactose is sourced from healthy animals under the same conditions as those intended for human consumption.

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 Oxytetracycline tablets BP 250mg (PL 17496/0003).

3 EXPERT REPORTS
The applicant has included detailed expert reports in the application. Signed declarations and copies of the experts’ CVs are enclosed 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 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
User testing of the package leaflet has been accepted, based on a bridging report provided by the applicant making reference to the user-testing of the PIL for Oxytetracycline 250 mg Tablets (PL 17496/0003). A critical analysis demonstrated that the key messages for safe and effective use for all leaflets were similar. The justification of the rationale for bridging is accepted.

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 and sufficient space for a standard UK pharmacy dispensing label.

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

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

No new clinical data have been supplied with this application and none are required for applications of this type.
OVERALL CONCLUSION AND RISK BENEFIT 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 applications of this type.

EFFICACY
This application is identical to the previously granted application for Oxytetracycline tablets BP 250 mg, first approved for Dalkeith Laboratories Ltd on 16th May 2000 (PL 17496/0003).

Pharmaceutical, non-clinical and clinical expert statements have been provided, together with CVs showing that the experts are appropriately qualified. The experts confirm that the product is identical in composition, manufacture and pharmaceutical characteristics to the respective reference product and that there are no toxicological or clinical issues.

No new or unexpected safety concerns arise from this application.

The SmPC, PIL and labelling are satisfactory and consistent with those for the cross-reference product.

RISK BENEFIT 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 oxytetracycline dihydrate is considered to have demonstrated the therapeutic values of the compounds. The risk benefit is, therefore, considered to be positive.
**STEPS TAKEN FOR ASSESSMENT**

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<th>The MHRA received the marketing authorisation application on 18&lt;sup&gt;th&lt;/sup&gt; April 2012</th>
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<td>Following standard checks and communication with the applicant the MHRA considered the application is valid on 28&lt;sup&gt;th&lt;/sup&gt; May 2012</td>
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<td>Following assessment of the application the MHRA requested further information on 30&lt;sup&gt;th&lt;/sup&gt; May 2012</td>
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<td>The applicant responded to the MHRA’s request, providing further information on 2&lt;sup&gt;nd&lt;/sup&gt; July 2012</td>
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<td>5</td>
<td>The application was determined on 22&lt;sup&gt;nd&lt;/sup&gt; August 2012</td>
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SUMMARY OF PRODUCT CHARACTERISTICS

In accordance with Directive 2010/84/EU the Summaries of Product Characteristics (SmPC) and Patient Information Leaflets (PIL) 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 Summaries of Product Characteristics (SmPC) and Patient Information Leaflets (PIL) for products granted Marketing Authorisations at a national level are available on the MHRA website.
UKPAR Oxytetracycline 250 mg Tablets

Each coated tablet contains Oxytetracycline 250mg (as Dihydrate). Also contains lactose, sucrose and E102. Please read the leaflet provided before use. For oral use as directed by the doctor.

**KEEP OUT OF THE REACH AND SIGHT OF CHILDREN**

Do not store above 25°C. Keep the container tightly closed.

Product Licence holder: Crescent Pharma Ltd., Pothampton Lane, Overton, Hampshire, RG25 9ED. PL 204160221