CETRABEN ORIGINAL EMOLLIENT CREAM
(PL 06831/0262)

UKPAR

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CETRABEN ORIGINAL EMOLLIENT CREAM
(PL 06831/0262)

LAY SUMMARY

On 10 October 2012, the MHRA granted Genus Pharmaceuticals Limited a Marketing Authorisation (licence) for the medicinal product Cetraben Original Emollient Cream. This is a general sales licence medicine (GSL) used as a moisturising and protective cream for the relief of symptoms, such as red, inflamed, damaged, dry or chapped skin, especially when associated with eczema.

This product contains the active substances white soft paraffin and light liquid paraffin. These help to smooth, soothe and hydrate skin and prevent moisture loss.

No new or unexpected safety concerns arose from this application and it was, therefore, judged that the benefits of taking Cetraben Original Emollient Cream outweigh the risks, hence a Marketing Authorisation has been granted.
CETRABEN ORIGINAL EMOLLIENT CREAM
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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 Cetraben Original Emollient Cream (PL 06831/0262) on 10 October 2012 to Genus Pharmaceuticals Limited.

This is an application for Cetraben Original Emollient Cream (PL 06831/0262), submitted as an abridged simple application according to Article 10c of Directive 2001/83/EC, cross-referring to Cetraben Emollient Cream (PL 06831/0259), which was originally granted to Pharma Healthcare Limited in 2000 (PL 17320/0001), but following a change of ownership in July 2011, the current marketing authorisation holder is Genus Pharmaceuticals Limited (PL 06831/0259).

The product contains the active substances white soft paraffin and light liquid paraffin. It is used as an emollient, moisturising and protective cream for the symptomatic relief of red, inflamed, damaged, dry or chapped skin, especially when associated with endogenous or exogenous eczema.
PHARMACEUTICAL ASSESSMENT

LICENCE NO:  PL 06831/0262
PROPRIETARY NAME: Cetraben Original Emollient Cream
ACTIVE(S): White soft paraffin and light liquid paraffin
COMPANY NAME: Genus Pharmaceuticals Limited
LEGAL STATUS: GSL

1. INTRODUCTION

This is a simple, piggyback application for Cetraben Original Emollient Cream submitted under Article 10c of Directive 2001/83/EC, as amended. The proposed MA holder is Genus Pharmaceuticals, Park View House, 65 London Road, Newbury, Berkshire, RG14 1JN, United Kingdom.

The application cross-refers to Cetraben Emollient Cream (PL 06831/0259), which was originally granted to Pharma Healthcare Limited in 2000 (PL 17320/0001), but following a change of ownership in July 2011, the current marketing authorisation holder is Genus Pharmaceuticals Limited (PL 06831/0259).

The current application is considered valid.

2. MARKETING AUTHORISATION APPLICATION FORM

2.1 NAME(S)
The proposed name of the product is Cetraben Original Emollient Cream. The product has been named in line with current requirements.

2.2 Strength, pharmaceutical form, route of administration, container and pack sizes
The finished product is to be packed into:
- polypropylene jars with a pump dispenser of 1050g, 500g, 150g and 50g,
- polyethylene screw capped jars or tubes of 125g,
- polyethylene tubes of 50g
- polyethylene tubes of 20g.

Not all pack sizes are to be marketed, however, the marketing authorisation holder has committed to submitting mock-ups to the relevant authorities for approval before marketing any pack size.

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 licence medicine (GSL).

2.4 Marketing authorisation holder/Contact Persons/Company
Genus Pharmaceuticals, Park View House, 65 London Road, Newbury, Berkshire, RG14 1JN, 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 product and the maximum batch sizes are 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 this product. This 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 (SmPC)
The proposed SmPC is consistent with the details registered for the cross-reference
product.

6. PATIENT INFORMATION LEAFLET (PIL)/CARTON
PIL/Labelling
The patient information leaflet/labelling has been prepared as one label/leaflet, in-line
with the details registered for the cross-reference product. 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 application are acceptable. From a quality perspective, a Marketing Authorisation should be granted.

NON-CLINICAL ASSESSMENT
No new non-clinical 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 important quality characteristics of Cetraben Original Emollient Cream 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 an application of this type.

CLINICAL PHARMACOLOGY/EFFICACY
No new clinical pharmacology/efficacy data have been submitted with this application and none are required for an application of this type.

SAFETY
No new safety data have been submitted with this application and none are required for an application of this type.

No new or unexpected safety concerns arise from this application.

The SmPC, PIL/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 white soft paraffin and light liquid paraffin is considered to have demonstrated the therapeutic value of the compound. The risk-benefit is, therefore, considered to be positive.
# CETRABEN ORIGINAL EMOLLIENT CREAM
## (PL 06831/0262)

### STEPS TAKEN FOR ASSESSMENT

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<th>Description</th>
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<tbody>
<tr>
<td>1</td>
<td>The MHRA received the marketing authorisation application on 6 October 2011</td>
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<td>2</td>
<td>Following standard checks and communication with the applicant, the MHRA considered the application valid on 11 November 2011</td>
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<td>3</td>
<td>Following assessment of the application, the MHRA requested further information relating to the dossiers on 15 February 2012 and 15 April 2012</td>
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<td>4</td>
<td>The applicant responded to the MHRA’s requests, providing further information on 16 March 2012 and 31 July 2012</td>
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<td>5</td>
<td>The application was determined on 10 October 2012</td>
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STEPS TAKEN AFTER AUTHORISATION - SUMMARY

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<thead>
<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/labelling
The current approved UK versions of the Summary of Product Characteristics (SmPC) and Patient Information Leaflet (PIL)/labelling for this product are available on the MHRA website.