CANESTEN HYDROCORTISONE
(clotrimazole and hydrocortisone acetate)

PL 00010/0644

UKPAR

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Lay Summary

The Medicines and Healthcare products Regulatory Agency (MHRA) granted to Bayer plc (trading as Bayer plc, Consumer Care Division) a Marketing Authorisation (licence) for the medicinal product Canesten Hydrocortisone (PL 00010/0644) on 19 April 2013. This medicine is a pharmacy (P) medicine, available only from pharmacies under the supervision of a pharmacist.

Canesten Hydrocortisone is used to treat athlete’s foot and fungal sweat rash when there are additional symptoms of inflammation (such as swelling, redness and itching).

Canesten Hydrocortisone treats the fungal skin infection and reduces the swelling and itching caused by it.

The active substances in Canesten Hydrocortisone are clotrimazole and hydrocortisone acetate. Clotrimazole belongs to a group of medicines called imidazoles, which destroy the fungi and some bacteria that cause skin infections. Hydrocortisone acetate is a mild steroid which reduces swelling, redness.

No new or unexpected safety concerns arose from this simple application and it was therefore judged that the benefits of using Canesten Hydrocortisone outweigh the risks and a Marketing Authorisation was granted.
CANESTEN HYDROCORTISONE
(clotrimazole and hydrocortisone acetate)

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SCIENTIFIC DISCUSSION

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INTRODUCTION

On 19 April 2013, the MHRA granted Bayer plc (trading as Bayer plc, Consumer Care Division) a Marketing Authorisation for the medicinal product Canesten Hydrocortisone (PL 00010/0644). The product is a pharmacy (P) medicine available from pharmacies and is indicated for the treatment of the following skin infections where co-existing symptoms of inflammation, e.g. itching, require rapid relief:
• athlete’s foot
• candidal intertigo.

This application was submitted as an abridged application according to Article 10c of Directive 2001/83/EC, as amended, cross-referring to Canesten Hydrocortisone (PL 00010/0216), which was granted a Marketing Authorisation to Bayer plc on 13 January 1997. Canesten Hydrocortisone (PL 00010/0216) cross-refers to Canesten Hydrocortisone (PL 00010/0120), which was granted a Marketing Authorisation in the UK to Bayer plc on 14 February 1984. Bayer plc has committed to stop marketing Canesten Hydrocortisone (PL 00010/0216) following the launch of Canesten Hydrocortisone (PL 00010/0644) on the market.

Canesten Hydrocortisone contains the active ingredients hydrocortisone acetate and clotrimazole. Clotrimazole, a synthetic imidazole derivative, is a broad spectrum antifungal. It also exhibits activity against *Trichomonas*, staphylococci, streptococci and *Bacteroides*. It has no effect on lactobacilli. Hydrocortisone acetate is one of the oldest corticosteroids used topically, for the treatment of inflammatory skin conditions such as pruritus and oedema, and is a standard low potency corticosteroid.

No new data were submitted nor were necessary for this simple application, as the data are identical to those of the previously granted cross-reference product.
# PHARMACEUTICAL ASSESSMENT

**LICENCE NO:** PL 00010/0644  
**PROPRIETARY NAME:** Canesten Hydrocortisone  
**ACTIVE(S):** Clotrimazole and hydrocortisone acetate  
**COMPANY NAME:** Bayer plc  
**E.C. ARTICLE:** Article 10c of Directive 2001/83/EC, as amended  
**LEGAL STATUS:** P

## 1. INTRODUCTION

This is an abridged application for Canesten Hydrocortisone, submitted under Article 10c of Directive 2001/83/EC, as amended.

The application cross-refers to Canesten Hydrocortisone (PL 00010/0216), which was authorised to Bayer plc on 13 January 1997. The current application is considered valid.

## 2. MARKETING AUTHORISATION APPLICATION FORM

### 2.1 Name(s)

The proposed name of the product is Canesten Hydrocortisone. The product has been named in line with current requirements.

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

The cream, for topical use, is packaged in aluminium tubes with internal lacquer coating and high-density polyethylene (HDPE) screw-on caps. These are packed into cardboard cartons with Patient Information Leaflets in pack size of 15 g.

The data from these studies support a shelf-life of 24 months for the unopened tube and 6 months for the opened tube, with the storage conditions ‘Do not store above 25°C.’

### 2.3 Legal status

On approval, the product will be available as a pharmacy medicine (P).

### 2.4 Marketing Authorisation Holder/Contact Persons/Company

Bayer plc, Bayer House, Strawberry Hill, Newbury, Berkshire, RG14 1JA, United Kingdom, trading as Bayer plc, Consumer Care Division.

The Qualified Person (QP) responsible for pharmacovigilance is stated and a satisfactory CV has been provided.

### 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 size is stated.

2.8 Finished product/shelf-life specification
The proposed finished product specification is in line with the details registered for the respective 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
None of the excipients contain materials of animal or human origin.

2.11 Bioequivalence
No bioequivalence data are required to support this simple abridged application because the proposed product is manufactured to the same formula and utilises the same processes as the reference product Canesten Hydrocortisone (PL 0010/0216).

3. EXPERT REPORT
The applicant cross-refers to the data for Canesten Hydrocortisone (PL 00010/0216), to which this application is claimed to be identical. This is acceptable.

4. PRODUCT NAME & APPEARANCE
See Section 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 Summary of Product Characteristics is consistent with the details registered for the cross-reference product.

6. PATIENT INFORMATION LEAFLET (PIL) AND LABELLING
PIL
The Patient Information Leaflet has been prepared in line with the details registered for the cross-reference product.

Bayer plc has previously submitted satisfactory PIL user testing for the PIL for Canesten Hydrocortisone (PL 00010/0216), in accordance with Article 59 of Council Directive 2001/83/EC.

User testing of the package leaflet for Canesten Hydrocortisone (PL 00010/0644) has been accepted based on the bridging report provided by the applicant making reference to the user-testing of the PIL for Canesten Hydrocortisone (PL 00010/0216), as the ‘parent PIL’. As the proposed and reference leaflets are considered the same, no further user testing of the leaflet for this product is considered necessary.
Carton and labels
The proposed artwork is consistent with 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.

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

As this is an abridged application submitted under Article 10c of Directive 2001/83/EC, as amended, 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 this product is intended for substitution with a product that is already marketed, no increase in environmental burden is anticipated. Thus, the justification for non-submission of an Environmental Risk Assessment is accepted.

The grant of a Marketing Authorisation is recommended.
CLINICAL ASSESSMENT

As this is an abridged application submitted under Article 10c of Directive 2001/83/EC, as amended, no new clinical data have been supplied and none are required.

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

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 profiles of the active ingredients are well-established.

The grant of a Marketing Authorisation is recommended.
OVERALL CONCLUSION AND BENEFIT/RISK ASSESSMENT

QUALITY
The data for this application is 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 this type of application.

EFFICACY
The application is identical to previously granted application for Canesten Hydrocortisone (PL 00010/0216).

SAFETY
No new safety data were supplied or required for this application. Clotrimazole and hydrocortisone acetate have well-established safety profiles. No new or unexpected safety concerns arose from this application.

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

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 cross-reference product. Extensive clinical experience with clotrimazole and hydrocortisone acetate is considered to have demonstrated the therapeutic value of the product. The benefit/risk balance is therefore considered to be positive.
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STEPS TAKEN FOR ASSESSMENT

1. The MHRA received the Marketing Authorisation applications on 29 December 2011.
2. Following standard checks and communication with the applicant the MHRA considered the applications valid on 17 April 2012.
3. Following assessment of the applications the MHRA requested further information relating to the dossier on 14 June 2012.
4. The applicant responded to the MHRA’s request, providing further information on the 12 December 2012.
5. The applications were granted on 19 April 2013.
STEPS TAKEN AFTER INITIAL PROCEDURE – SUMMARY

The following table list a non-safety update to the Marketing Authorisation for this product that have been approved by the MHRA since the product was first licensed.

<table>
<thead>
<tr>
<th>Date submitted</th>
<th>Application type</th>
<th>Scope</th>
<th>Outcome</th>
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<td>26/04/2013</td>
<td>Type IA</td>
<td>To register the replacement of the Detailed Description of Pharmacovigilance System (DDPS) by the introduction of the Summary of the Pharmacovigilance System Master File. Consequently, the details of the Qualified Person for Pharmacovigilance have been changed.</td>
<td>Approved 16/05/2013</td>
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SUMMARY OF PRODUCT CHARACTERISTICS

In accordance with Directive 2010/84/EU, the Summaries of Product Characteristics (SmPCs) 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 Patient Information Leaflets (PILs) for products granted Marketing Authorisations at a national level are available on the MHRA website.
Please read the leaflet carefully before use.

Directions: The cream should be evenly and thinly applied twice daily to the affected area and rubbed in gently. Do not use for more than seven days. If symptoms persist consult your doctor.

Each gram of cream contains 10mg clotrimazole and 11.2mg hydrocortisone acetate (equivalent to 10mg hydrocortisone).

The cream also contains benzyl alcohol, ceteareth alcohol, triceteareth-4-phosphate, medium chain triglycerides, purified water, sodium hydroxide and hydrochloric acid (see the leaflet for further information).

Keep out of reach and sight of children. Do not store above 25°C.

MA Holder: Bayer plc, Consumer Care Division
Newbury, Berkshire, RG14 1JA, U.K.
Pl 00010/0644

15g For external use only P

Canesten®

Hydrocortisone

Clotrimazole & Hydrocortisone acetate

Triple action formula treats sweat rash and athlete's foot

Groundwater