Canesten Thrush Internal Cream 10% w/w vaginal cream

(clotrimazole)

PL 00010/0654

UKPAR

Bayer plc
LAY SUMMARY

Canesten Thrush Internal Cream 10% w/w vaginal cream

(clotrimazole)

This is a summary of the Public Assessment Report (PAR) for Canesten Thrush Internal Cream 10% w/w vaginal cream (PL 00010/0654). It explains how the application for Canesten Thrush Internal Cream 10% w/w vaginal cream was assessed and its authorisation recommended, as well as the conditions of use. It is not intended to provide practical advice on how to use Canesten Thrush Internal Cream 10% w/w vaginal cream.

For practical information about using Canesten Thrush Internal Cream 10% w/w vaginal cream, patients should read the package leaflet or contact their doctor or pharmacist.

The product may be referred to as ‘Canesten Thrush Internal Cream’ in this report.

What is Canesten Thrush Internal Cream and what is it used for?
This medicine is the same as Canesten Internal Cream (PL 00010/0136; Bayer plc), which is already authorised in the UK. The licence holder (Bayer plc) for Canesten Internal Cream (PL 00010/0136) has agreed that its own scientific data can be used as a basis for the grant of an identical licence for Canesten Thrush Internal Cream (PL 00010/0654) (informed consent).

Canesten Thrush Internal Cream is a single application, full course treatment for vaginal thrush. It is a soothing intravaginal cream in a prefilled applicator for treatment at the site of infection. This product should only be used if the patient has previously been diagnosed by her doctor as having vaginal thrush.

How does Canesten Thrush Internal Cream work?
The active ingredient in Canesten Thrush Internal Cream is clotrimazole, which belongs to a group of medicines called azoles. Clotrimazole is an antifungal agent which fights the cause of infections such as vaginal thrush.

How is Canesten Thrush Internal Cream used?
Canesten Thrush Internal Cream is available in single-dose packs containing 5g of white vaginal cream. Canesten Thrush Internal Cream is administered vaginally. The cream should not be put in the mouth or swallowed.

If Canesten Thrush Internal Cream has been prescribed, the patient should follow any instructions the prescribing doctor may have given. If the patient has purchased the product without a prescription, she should follow the instructions in the package leaflet.

Canesten Thrush Internal Cream is not recommended in children under 16 years.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

Canesten Thrush Internal Cream can be obtained without a prescription, at pharmacies under the supervision of a pharmacist.
What benefits of Canesten Thrush Internal Cream have been shown in studies?
The application for Canesten Thrush Internal Cream (PL 00010/0654) is considered to be identical to the previously authorised licence for Canesten Internal Cream (PL 00010/0136; Bayer plc), with the same benefits and risks. So, no new studies have been provided for Canesten Thrush Internal Cream (PL 00010/0654). However, reference is made to the studies for Canesten Internal Cream (PL 00010/0136; Bayer plc).

What are the possible side effects from Canesten Thrush Internal Cream?
Like all medicines, Canesten Thrush Internal Cream can cause side effects, although not everybody gets them.

For the full list of all side effects reported with Canesten Thrush Internal Cream, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Canesten Thrush Internal Cream approved?
No new or unexpected safety concerns arose from this application. The MHRA, therefore, considered that the benefits of Canesten Thrush Internal Cream outweigh their risks; and the grant of a Marketing Authorisation was recommended.

What measures are being taken to ensure the safe and effective use of Canesten Thrush Internal Cream?
A Risk Management Plan has been developed to ensure that Canesten Thrush Internal Cream is used as safely as possible. Based on this plan, safety information has been included in the Summary of Product Characteristics and the package leaflet for Canesten Thrush Internal Cream, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously.

Other information about Canesten Thrush Internal Cream
A Marketing Authorisation was granted in the UK to Bayer plc on 07 January 2016.

The full PAR for Canesten Thrush Internal Cream follows this summary.

For more information about treatment with Canesten Thrush Internal Cream, read the package leaflet, or contact your doctor or pharmacist.

This summary was last updated in March 2016.
Canesten Thrush Internal Cream 10% w/w vaginal cream

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SCIENTIFIC DISCUSSION

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INTRODUCTION

The Medicines and Healthcare products Regulatory Agency (MHRA) granted Bayer plc a Marketing Authorisation for the medicinal product Canesten Thrush Internal Cream 10% w/w vaginal cream (PL 00010/0654) on 07 January 2016. The product is a Pharmacy (P) medicine indicated for the treatment of candidal vaginitis.

The application was submitted as a simple abridged (informed consent) application according to Article 10c of Directive 2001/83/EC, as amended. Canesten Thrush Internal Cream 10% w/w vaginal cream (PL 00010/0654) cross-refers to the reference product Canesten Internal Cream (PL 00010/0136), granted to Bayer plc Consumer Care on 30 January 1985.

Canesten Thrush Internal Cream 10% w/w vaginal cream contains the active ingredient, clotrimazole. Clotrimazole acts against fungi by inhibiting ergosterol synthesis. Inhibition of ergosterol synthesis leads to structural and functional impairment of the fungal cytoplasmic membrane. Clotrimazole has a broad antimycotic spectrum of action in vitro and in vivo, which includes dermatophytes, yeasts and moulds.

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

1. INTRODUCTION
This is an informed consent application for Canesten Thrush Internal Cream 10% w/w vaginal cream (PL 00010/0654) submitted under Article 10c of Directive 2001/83/EC, as amended.

The application cross-refers to Canesten Internal Cream (PL 00010/0136), granted to Bayer plc Consumer Care on 30 January 1985. The application is considered valid.

2. MARKETING AUTHORISATION APPLICATION FORM

2.1. Name
The proposed name of the product is Canesten Thrush Internal Cream 10% w/w vaginal cream. The product has been named in line with current requirements.

2.2. Strength, pharmaceutical form, route of administration, container and pack sizes
Canesten Thrush Internal Cream 10% w/w vaginal cream contains clotrimazole 10% w/w as the active substance and is administered vaginally. Canesten Thrush Internal Cream 10% w/w vaginal cream is supplied as a single dose applicator consisting of a body of high density polyethylene (lupolene or hostalene), piston of low density polyethylene (LDPE), cap of LDPE, with a separate plunger of polystyrene. One applicator is contained in a blister pack. The product is available in a pack size of 5g.

The proposed shelf life for the product is 2 years, with the special storage conditions ‘Do not store above 25°C.’

The packaging, proposed shelf-life and storage conditions are consistent with the details registered for the cross-reference product.

2.3. Legal status
The product is available as a Pharmacy (P) medicine.

2.4. Marketing Authorisation Holder/Contact Persons/Company
Bayer plc, Bayer House, Strawberry Hill, Newbury, Berkshire, RG14 1JA.

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 consistent 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
None of the excipients contains materials of animal or human origin. This is consistent with the cross-reference product.

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 Internal Cream (PL 00010/0136; Bayer plc).

3. EXPERT REPORT
The applicant cross-refers to the data for Canesten Internal Cream (PL 00010/0136; Bayer plc) 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 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) AND LABELLING
PIL
The PIL has been prepared in line with the details registered for the cross-reference product.

User-testing of the PIL for Canesten Thrush Internal Cream 10% w/w vaginal cream (PL 00010/0654) has been accepted based on the successful user-testing of the PIL for the reference product Canesten Combi Pessary and Cream (GSL) as the ‘parent PIL’.

Carton and label
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 is acceptable. The grant of a Marketing Authorisation is recommended.
NON-CLINICAL ASSESSMENT

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

Suitable justification has been provided for non-submission of an Environmental Risk Assessment. As the application is an identical version of an already authorised product, it is not expected that environmental exposure will increase following approval of the Marketing Authorisation for the proposed product.

The grant of a Marketing Authorisation is recommended.
CLINICAL ASSESSMENT

As this is an informed consent 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.

An acceptable Risk Management Plan (RMP) has been submitted. A summary of safety concerns is listed in the following table.

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<th>Summary of safety concerns</th>
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Routine risk minimisation is provided through the Summary of Product Characteristics and the Patient Information Leaflet and this is sufficient.

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

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
This application is identical to the previously granted licence for Canesten Internal Cream (PL 00010/0136; Bayer plc).

SAFETY
No new safety data were supplied or required for this application. Clotrimazole has a well-established safety profile. No new or unexpected safety concerns arose from this application.

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

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