Terbinafine 250mg Tablets

(terbinafine hydrochloride)

PL 08553/0213

UK Public Assessment Report

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Medicines and Healthcare Products Regulatory Agency

Terbinafine 250mg Tablets
(terbinafine hydrochloride)

LAY SUMMARY

This is a summary of the Public Assessment Report (PAR) for Terbinafine 250mg Tablets (PL 08553/0213). It explains how the application for Terbinafine 250mg Tablets 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 Terbinafine 250mg Tablets.

For practical information about using Terbinafine 250mg Tablets, patients should read the package leaflet or contact their doctor or pharmacist.

The product may be referred to as Terbinafine Tablets in this report.

What are Terbinafine Tablets and what are they used for?

This medicine is the same as Terbinafine 250mg Tablets (PL 08553/0186), which is already authorised in the UK. The licence holder (Dr Reddy's Laboratories (UK) Limited) for Terbinafine 250mg Tablets (PL 08553/0186) has agreed that its own scientific data can be used as a basis for the grant of an identical licence for Terbinafine 250mg Tablets (PL 8553/0213) (informed consent).

Terbinafine Tablets are an antifungal medicine used in adults to treat fungal skin and nail infections.

How do Terbinafine Tablets work?

Terbinafine Tablets contain the active ingredient terbinafine (as terbinafine hydrochloride), which kills fungi that cause skin and nail infections.

How are Terbinafine Tablets used?

Terbinafine Tablets are taken by mouth. The tablets/tablet halves should be swallowed whole with a glass of water.

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

Terbinafine Tablets can only be obtained with a prescription.

What benefits of Terbinafine Tablets have been shown in studies?

The application for Terbinafine Tablets is considered to be identical to the previously authorised licence for Terbinafine 250mg Tablets (PL 08553/0186; Dr Reddy's Laboratories (UK) Limited), with the same benefits and risks. So, no new studies have been provided for Terbinafine Tablets. However, reference is made to the studies or Terbinafine 250mg Tablets (PL 08553/0186; Dr Reddy's Laboratories (UK) Limited).

What are the possible side effects from Terbinafine Tablets?

Like all medicines, Terbinafine Tablets can cause side effects, although not everybody gets them.

For the full list of all side effects reported with Terbinafine Tablets, see section 4 of the package leaflet.

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

Why are Terbinafine Tablets approved?

No new or unexpected safety concerns arose from this application. The MHRA, therefore, considered that the benefits of Terbinafine Tablets 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 Terbinafine Tablets?

Safety information has been included in the Summary of Product Characteristics and the package leaflet for Terbinafine Tablets 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 Terbinafine Tablets.

A Marketing Authorisation was granted in the UK on 13 December 2005.

The full PAR for Terbinafine Tablets follows this summary.

For more information about treatment with Terbinafine Tablets, read the package leaflet, or contact your doctor or pharmacist.

This summary was last updated in May 2015.

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SCIENTIFIC DISCUSSION

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INTRODUCTION

The UK granted a Marketing Authorisation for the medicinal product Terbinafine 250mg Tablets (PL 08553/0213) to Dr Reddys Laboratories (UK) Ltd on 13 December 2005. The product is a prescription only medicine.

The application was submitted as a simple abridged application according to Article 10.1(a)(i) of Directive 2001/83/EC, cross-referring to Terbinafine 250mg Tablets (PL 08553/0186), approved on 08 January 2004. This standard abridged application had, in turn, demonstrated their essential similarity to Lamisil 250mg Tablets, approved on 03 October 1990.

No new data was submitted nor was it necessary for this simple application, as the data is identical to that of the previously granted cross-reference product. As the cross-reference product was granted prior to the introduction of current legislation, no PAR was generated for them.

The product contains the active ingredient terbinafine hydrochloride which is an antifungal agent indicated for the treatment of both nail and skin infections. Terbinafine tablets are indicated for dermatophyte infections of the nails, ringworm infections (including tinea pedis, cruris and corporis) when oral therapy is appropriate due to site, severity or extent.

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

PHARMACEUTICAL ASSESSMENT

LICENCE NO: PL 08553/0213
PROPRIETARY NAME: Terbinafine 125mg Tablets
ACTIVE(S): Terbinafine Hydrochloride
COMPANY NAME: Dr. Reddys Laboratories (UK) Limited
E.C. ARTICLE: Article 10.1(a)(i) of Directive 2001/83/EC
LEGAL STATUS: POM

1. INTRODUCTION

This is a simple, piggy back application for Terbinafine 250mg Tablets submitted under Article 10.1(a)(i) of Directive 2001/83/EC. The proposed MA holder is "Dr. Reddy's Laboratories (UK) Ltd, 6, Riverview Road, Beverley, East Yorks, HU17 0LD."

This application cross refers to standard abridged application for Terbinafine 250mg tablets (PL 08553/0186) which is currently registered in the UK. This application is considered valid.

2. MARKETING AUTHORISATION APPLICATION FORM

2.1 Name(s)
The proposed name of the product are Terbinafine 250mg 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 contain terbinafine hydrochloride equivalent to 250mg of terbinafine. The produc is to be stored in polyethylene containers of 60 and 500 tablets or blister packs of 14 and 28 tablets. The proposed shelf-life (3 years) and storage conditions (Do not store above 25^{o}C; Keep in the original container; Keep blister in outer carton) are consistent with the details registered cross-reference products.

2.3 Legal status
On approval, the product will be subject to a medical prescription.

2.4 Marketing authorisation holder/Contact Persons/Company
The proposed Marketing Authorisation holder is Dr. Reddy's Laboratories (UK) Ltd, 6, Riverview Road, Beverley, East Yorks, HU17 0LD

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 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 productsand 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 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 the product. This is consistent with the cross reference product for which magnesium stearate was confirmed as being of vegetable origin.

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 AND 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/CARTON
PIL
The patient information leaflet has been prepared in-line with the details registered for the cross-reference product

Carton and blister
The proposed artwork is comparable to 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 and has included sufficient space for a standard UK pharmacy dispensing label.

7. CONCLUSIONS
The data submitted with the application are acceptable. A Marketing Authorisation should be granted.

PRECLINICAL ASSESSMENT

No new preclinical data have been supplied with this application and none are required for an application of this type.

CLINICAL ASSESSMENT

As this is a duplicate application for PL 08553/0186, no new clinical data have been supplied and none are required.

OVERALL CONCLUSION AND RISK BENEFIT ASSESSMENT

QUALITY
The data for this application are consistent with that previously assessed for the cross-reference product and as such has been judged to be satisfactory.

PRECLINICAL
No new preclinical data were submitted and none are required for this type of application.

EFFICACY
Terbinafine is a well known drug and has been used as an anti-fungal agent for many years. This application is identical to previously granted application for Terbinafine Tablets (PL08553/0186) in which the applicant demonstrated essential similarity to the innovator product, Lamisil 250mg Tablets.

No new or unexpected safety concerns arise from this application.

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

RISK BENEFIT ASSESSMENT
The quality of the product is acceptable and no new preclinical or clinical safety concerns have been identified. The applicant's product is identical to the cross-reference product which, in turn, has been shown to be interchangeable with the innovator product. Extensive clinical experience with terbinafine is considered to have demonstrated the therapeutic value of the compound. The risk benefit is therefore considered to be positive.

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STEPS TAKEN FOR ASSESMENT

1	The MHRA received the Marketing Authorisation application on 08/03/2004.
2	Following standard checks and communication with the applicant the MHRA considered the application valid on 10/01/2005.
3	Following assessment of the application the MHRA requested further information on 08/02/2005, 28/06/2005, 02/08/2005 and 29/11/2005.
4	The applicant responded to the MHRA's requests, providing further information on 03/03/2005, 28/06/2005, 17/11/2005 and 09/12/2005.
7	The application was determined on 13/12/2005.

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STEPS TAKEN AFTER ASSESSMENT

Date submitted	Application type	Scope	Outcome
19 March 2015	Type 1B	To update the Summary of Product Characteristics (SmPC), sections 2, 3, 4.1, 4.2, 4.3, 4.4, 4.5, 4.6, 4.8, 5.1, 5.2 in line with the originator, Lamisil (Novartis) and current the Quality Review of Documents (QRD) template. As a consequence, the labelling and leaflet have been updated.	Approved 20 April 2015

SUMMARY OF PRODUCT CHARACTERISTICS

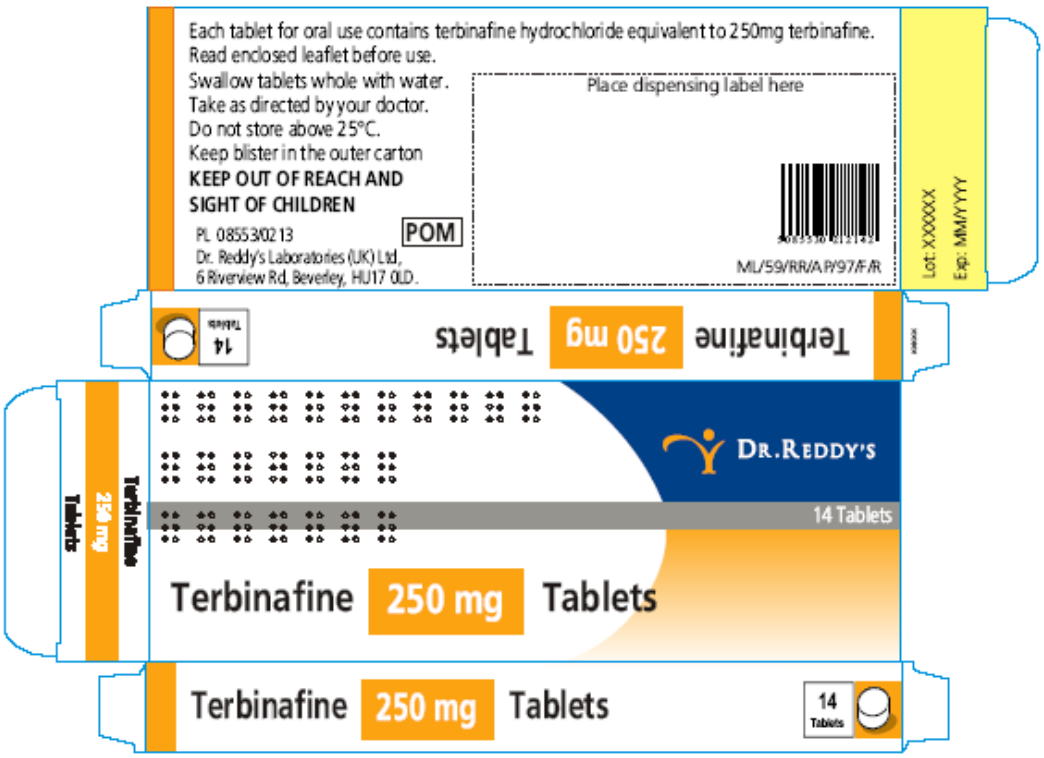
In accordance with Directive 2010/84/EU, the Summaries of Product Characteristics (SmPCs) for products granted Marketing Authorisations at a national level are available on the MHRA website.

PATIENT INFORMATION LEAFLET

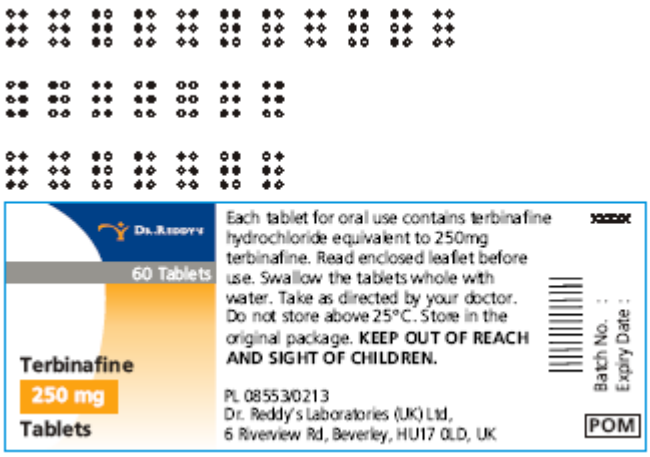
In accordance with Directive 2010/84/EU, the Patient Information Leaflets (PILs) for products granted Marketing Authorisations at a national level are available on the MHRA website.

LABELLING

CARTON



CONTAINER



Annex 1

Our Reference: PL 08553/0213 - 0032
Product: PL 08553/0213 DR REDDYS LABS UK TERBINAFINE TABLETS 250MG
Marketing Authorisation Holder: DR REDDY'S LABORATORIES (UK) LIMITED
Active Ingredient(s): TERBINAFINE HYDROCHLORIDE.

Type of Procedure: National
Submission Type: Variation
Submission Category: Type IB
Submission Complexity: Standard
EU Procedure Number (if applicable):

Reason:
To update the Summary of Product Characteristics (SmPC), sections 2, 3, 4.1, 4.2, 4.3, 4.4, 4.5, 4.6, 4.8, 5.1, 5.2 in line with the originator, Lamisil (Novartis) and current the Quality Review of Documents (QRD) template. As a consequence, the labelling and leaflet have been updated.

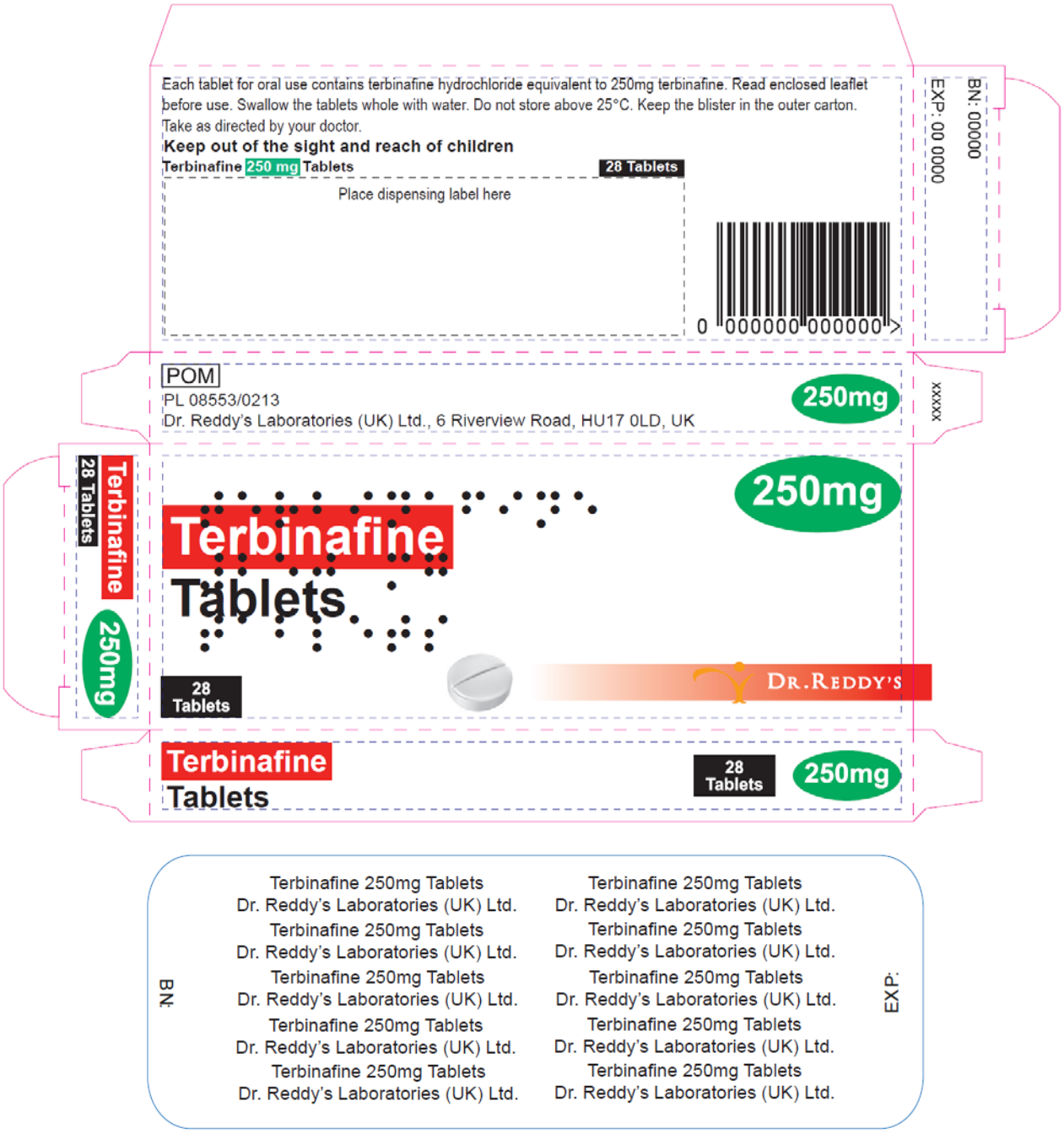
Linked / Related Variation(s) or Case(s):
Not applicable.

Supporting Evidence
Revised SmPC fragments (sections), and updated labelling and leaflet have been provided.

Evaluation
The updated sections of the SmPC,the updated labelling and leaflet are satisfactory.

Conclusion
The updated sections of the SmPC, the updated labelling and the leaflet are satisfactory and there are no objections to approval.

In accordance with Directive 2010/84/EU the Summaries of Product Characteristics (SmPCs) and Patient Information Leaflets (PILs) for products granted Marketing Authorisations at a national level are available on the MHRA website. The revised labelling is presented below.



Decision - Approved on 20 April 2015