

Public Assessment Report
Carnation Athlete's Foot Powder
Tolnaftate
PL 00089/0012
Cuxson Gerrard and Company Limited

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Lay Summary

The MHRA has granted a Marketing Authorisation (licence) to Cuxson Gerrard and Company Limited for Carnation Athlete's Foot Powder on 26/04/2007. The applicant successfully claimed the product was a generic medical product of Scholl's Athlete's Foot Powder.

The product contains the active ingredient Tolnaftate, which is an antifungal which inhibits the fungi responsible for cutaneous athlete's foot infections. Carnation Athlete's Foot Powder is indicated in the treatment of athlete's foot.

Scientific Discussion

INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the UK granted marketing authorisations for the medicinal product Carnation Athlete's Foot Powder (PL 00089/0012) on 26/04/2007.

The applicant successfully claimed the product was a generic medical product of Scholl's Athlete's Foot Powder 1% under Article 10.1 of EC Directive 2001/83/EC, The reference product PL 00587 / 0007 held by Scholl Consumer Products Limited, granted April 1985.

The product contains the active ingredient Tolnaftate, which is an antifungal which inhibits the fungi responsible for cutaneous athlete's foot infections. Carnation Athlete's Foot Powder is indicated in the treatment of athlete's foot.

PHARMACEUTICAL ASSESSMENT

DRUG SUBSTANCE

An appropriate specification based on the European Pharmacopoeia has been provided for Tolnaftate.

Analytical methods have been appropriately validated and are satisfactory for ensuring compliance with the relevant specifications.

Batch analysis data are provided and comply with the proposed specification.

Satisfactory certificates of analysis have been provided for working standards used by the active substance manufacturer and finished product manufacturer during validation studies.

Appropriate stability data have been generated.

DRUG PRODUCT

Other Ingredients

The other ingredients of the drug product are purified talc and maize starch sterilizable. The two excipients comply with their Ph Eur monograph, satisfactory details of tests performed on receipt and Certificates of Analysis were provided. No ingredients are of animal or human origin.

Dissolution and impurity profiles

Dissolution and impurity profiles for both strengths of drug product were found to be similar to those for the reference products.

Manufacture

A description and flow-chart of the manufacturing method has been provided.

In-process controls are appropriate considering the nature of the product and the method of manufacture. Process validation has been carried out on batches of each strength. The results are satisfactory.

Finished product specification

The finished product specification is satisfactory. Acceptance limits have been justified with respect to conventional pharmaceutical requirements and, where appropriate, safety. Test methods have been described and have been adequately validated, as appropriate. Batch data have been provided and comply with the release specification. Certificates of analysis have been provided for any working standards used.

Container Closure System

The product is contained in a High Density polythene jar with a polypropylene sprinkle insert. The packaging meets current requirements.

Stability

Finished product stability studies have been conducted in accordance with current guidelines. Based on the results, a shelf-life of 3 years has been set, which is satisfactory. Storage conditions are “Do not store above 25 degrees”.

ASSESSOR’S OVERALL CONCLUSIONS ON QUALITY AND ADVICE

A Marketing Authorisation was granted.

PRE-CLINICAL ASSESSMENT

No new pre-clinical data were provided and none were required for this application.

MEDICAL ASSESSMENT

Clinical Pharmacology

Carnation Athlete's Foot Powder is administered as a topical powder. Pharmacokinetic data are therefore not included in this report.

Pharmacodynamics

Tolnaftate inhibits the growth of the dermatophytes, *Epidermophyton*, *Microsporum*, *Trichophyton sp.*, and *Malassezia furfur*. Its mode of action is via the inhibition of the biosynthesis of ergosterol, the main sterol in the cell wall of these fungi.

Bioequivalence.

The medical assessor was willing to accept in-vitro data to demonstrate bioequivalence, given the nature of the product and route of administration, in lieu of comparative efficacy studies. The test product and the reference product were therefore compared in an in-vitro test of anti-microbial activity.

The activity of these powders (CG Athlete's foot powder, Scholl Athlete's foot powder and CG Athlete's foot powder excipient alone as control) have been assessed in an in-vitro test of anti-microbial activity. The test was a minimum inhibitory concentration investigation in semi solid agar gel using the common dermatophyte fungal micro organisms as the test organisms-Trichophyton rubrum and Trichophyton mentagrophytes. The test showed that both the CG and Scholl powders had marked anti-microbial properties against both dermatophyte micro organisms.

To confirm the essential similarity of the CG athlete's foot powder with the already licensed Scholl foot powder a particle size distribution study was performed. The distribution of particle sizes of the CG foot powder and the already licensed Scholl athlete's foot powder was found to be almost identical.

These results support the claim that the test product is a generic medical product of Scholl's Athlete's Foot Powder.

Efficacy

No formal efficacy data have been provided for this application.

Safety

No formal safety data have been provided for this application.

Clinical Expert Report

A satisfactory clinical expert report was provided, written by a suitably qualified expert.

Summary of Product Characteristics

A satisfactory Summary of Product Characteristics was arrived at during the procedure.

Leaflet/Label

Satisfactory combined labels and leaflets were provided.

Conclusion

A Marketing Authorisation was granted.

Overall Conclusion and Risk/Benefit Analysis

Quality

The important quality characteristics of Carnation Athlete's Foot Powder are well defined and controlled. There are no outstanding quality issues that would have a negative impact on the benefit/risk balance.

Pre-Clinical

No new pre-clinical data was provided and none was required for this application.

Clinical

Bioequivalence has been demonstrated between the applicant's product and the reference product. No new or unexpected safety concerns arise from these applications.

The SPC, PIL and labelling are satisfactory and consistent with that for the reference product.

Risk/Benefit Analysis

The quality of the product is acceptable and no new preclinical or clinical safety concerns have been identified. The bioequivalence study supports the claim that the applicant's products and the innovator products are interchangeable. The risk benefit is, therefore, considered to be positive.

Steps Taken During Assessment

1	The MHRA received the application on 01/11/2002.
2	Following standard checks and communication with the applicant the MHRA considered the application valid on 06/12/2002.
3	Following assessment of the application the MHRA requested further information from the applicant regarding the quality assessment on 08/04/2003 and 09/07/2004 on the medical assessment on 10/01/2003, 01/04/2003 and 08/11/2004.
4	The applicant provided further information in regard to the quality assessment on 12/02/2004, 23/08/2004 and on the medical assessment on 17/03/2003, 25/08/2005 and 18/04/2007.
5	The application was determined on 26/04/2007.

Steps Taken after Assessment

None

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Carnation Athlete's Foot Powder 1% w/w tolnaftate topical powder
Superdrug Athlete's Foot Powder 1% w/w tolnaftate topical powder
Tesco Medicated Athlete's Foot Powder 1% w/w tolnaftate topical powder

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Tolnaftate 1.0 % w/w.
For excipients see 6.1.

3 PHARMACEUTICAL FORM

Powder topical
A white to off white powder, free from grittiness.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the treatment and prevention of athlete's foot.

4.2 Posology and method of administration

Wash the feet and dry carefully between the toes.
For adults, children and the elderly: Turn top of pack to open. Apply twice daily, morning and night, by dusting the feet liberally, especially between the toes. Treatment should be continued for up to two weeks after the symptoms disappear. Repeat courses may be required. The powder may also be used to dust the insides of footwear and hosiery.
Do not use on broken or sensitive skin.

4.3 Contraindications

Allergy to tolnaftate or any of the ingredients.

4.4 Special warnings and precautions for use

For external use only.
Keep out of eyes.
Keep out of reach of children.
If symptoms persist consult your doctor.
Diabetics should seek professional advice before using any foot care product.
Not recommended for nail or scalp infections.

4.5 Interaction with other medicinal products and other forms of interaction

Not applicable

4.6 Pregnancy and lactation

Based on available published data there is no requirement to contraindicate the use of the product during pregnancy and lactation.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

Rarely may cause minor skin irritation

4.9 Overdose

Not applicable.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Tolnaftate is an antifungal which inhibits the fungi responsible for cutaneous athlete's foot infections.

5.2 Pharmacokinetic properties

Not applicable for a topical dosage form of this type.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber other than that which is already included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Talc (Talc purified),
Starch maize sterilisable.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container
HDPE jar fitted with a polypropylene Rotec sprinkler cap, containing 75 g.

6.6 Special precautions for disposal
Not Applicable

7 MARKETING AUTHORISATION HOLDER

Cuxson Gerrard & Company Limited
125 Broadwell Road
Oldbury
West Midlands
B69 4BF

8 MARKETING AUTHORISATION NUMBER(S)

PL 00089/0012

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

26/04/2007

10 DATE OF REVISION OF THE TEXT

26/04/2007

Labels and Leaflet

Carnation Athlete's Foot Powder contains Tolnaftate, a powerful antifungal for the treatment and prevention of Athlete's Foot. Each application destroys the fungi that cause Athlete's Foot and leaves behind powerful protection to maintain healthy skin. Regular use will help to prevent reinfection.

DIRECTIONS FOR USE
Wash the feet and dry carefully between the toes. For adults, children and the elderly: Turn top of pack to open. Apply twice daily, morning and night, by dusting the feet liberally, especially between the toes. Treatment should be continued for two weeks after symptoms disappear. Repeat courses may be required. The powder may also be used to dust the insides of footwear and hosiery. If you miss an application, apply it as soon as you remember


WARNINGS
FOR EXTERNAL USE ONLY
Keep out of the reach and sight of children. Rarely, may cause minor skin irritation. If symptoms persist or if there are any other effects consult your Doctor or Pharmacist. Avoid contact with the eyes. Do not use after expiry date shown. Do not use if allergic to Tolnaftate or any of the ingredients. Do not use on broken or sensitive skin. Diabetics should seek professional medical advice before using any footcare product. Not recommended for nail or scalp infections. Active Ingredient: Tolnaftate 1% w/w. Also contains: Sterilized Talc, Corn Starch. Do not store above 25°C. PL 00089/0012 Date of Information November 2003 Carnation is a registered trade mark of Cuxson Gerrard.

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Manufacturer Penn Pharmaceutical Services Ltd., Gwent NP22 3AA.
Product Licence Holder Cuxson Gerrard & Co. Ltd.,
125 Broadwell Road, Oldbury, West Midlands, England B69 4BF.



ATHLETE'S FOOT POWDER

1% w/w tolnaftate topical powder

- Destroys the fungi that cause Athlete's Foot
- Relieves itching & soreness
- Fast powerful treatment



Superdrug Athlete's Foot Powder is a topical (used on the skin) antifungal for the treatment and prevention of Athlete's Foot. Each application leaves behind powerful protection helping to maintain healthy skin. Regular use will help to prevent reinfection.

DIRECTIONS FOR USE: Wash the feet and dry carefully between the toes. For adults, children and the elderly: Turn top of pack to open. Apply twice daily, morning and night, by dusting the feet liberally, especially between the toes. Treatment should be continued for two weeks after the symptoms disappear. If you miss an application, apply it as soon as you remember. Repeat courses may be required. The powder may also be used to dust the inside of footwear and hosiery.

FOR EXTERNAL USE ONLY. AVOID CONTACT WITH THE EYES. NOT RECOMMENDED FOR NAIL OR SCALP INFECTIONS. RARELY MAY CAUSE MINOR SKIN IRRITATION. IF SYMPTOMS DO NOT GO AWAY OR WORSEN OR IF THERE ARE ANY OTHER EFFECTS, TALK TO YOUR PHARMACIST OR DOCTOR. DO NOT USE ON BROKEN OR SENSITIVE SKIN. DO NOT USE IF ALLERGIC TO TOLNAFTATE OR ANY OF THE INGREDIENTS. KEEP OUT OF THE REACH AND SIGHT OF CHILDREN. DIABETICS SHOULD SEEK PROFESSIONAL ADVICE BEFORE USING ANY FOOTCARE PRODUCT. DO NOT USE AFTER EXPIRY DATE SHOWN.

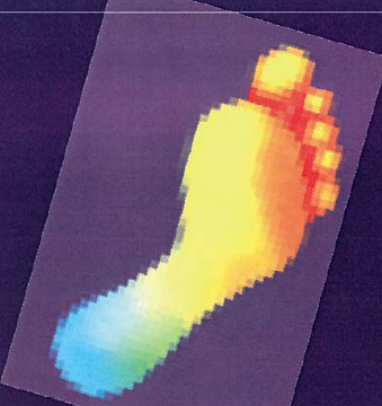
Active Ingredient
Tolnaftate Ph. Eur. 1% w/w
Also contains: Sterilized Talc, Corn Starch
Do not store above 25°C.

Prepared and packaged for Superdrug Stores plc
Product Licence Holder Cuxson Gerrard & Co. Ltd.
125 Broadwell Road, Oldbury, West Midlands B69 4BF
Manufacturer Penn Pharmaceutical Services Ltd.
Gwent, Gwent NP22 3AA
PL 00089/0012
Date of information
May 2003

90%
BARCODE PRINTS
PMS 270c

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Superdrug Stores plc
Admiral House, Croydon, U.K. CR9 4WZ



superdrug

athlete's foot powder
1% w/w Tolnaftate topical powder
Treats and prevents Athlete's Foot

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We are here to help:
Tesco Stores Ltd., Chestnut EN8 9SL, U.K.
Freephone 0800 50 55 55
www.tesco.com

Additional information

Manufacturer Penn Pharmaceutical Services Ltd., Gwent NP23 3AA
Product Licence Holder Cuxson Gerrard & Co. Ltd., Broadwell Road, Oldbury, West Midlands B69 4BF
Date of information November 2003

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Athlete's foot powder

1% w/w Tolnaftate topical powder

- Destroys the fungi that cause Athlete's foot
- Relieves itching and soreness
- Fast powerful treatment

Tesco Athlete's foot powder.
Contains Tolnaftate, a powerful antifungal for the treatment and prevention of Athlete's foot.

- Each application destroys the fungi that cause Athlete's foot and leaves behind powerful protection to maintain healthy skin.
- Regular use will help to prevent re-infection.

Directions for use

1. Wash the feet and dry carefully between the toes.
2. For adults, children and the elderly: Turn top of pack to open.
3. Apply twice daily, morning and night, by dusting the feet liberally, especially between the toes.
4. Treatment should be continued for two weeks after symptoms disappear.
5. Repeat courses may be required. The powder may also be used to dust the insides of footwear and hosiery.
6. If you miss an application, apply it as soon as you remember.

Storage

Do not store above 25°C.

Warning

For external use only.

Keep out of the reach and sight of children.

- Rarely, may cause minor skin irritation.
- If symptoms persist or if there are any other effects consult your Doctor or Pharmacist.
- Avoid contact with the eyes.
- Do not use after expiry date shown.
- Do not use if allergic to Tolnaftate or any of the ingredients.
- Do not use on broken or sensitive skin.
- Diabetics should seek professional medical advice before using any footcare product.
- Not recommended for nail or scalp infections.

Ingredients

Active ingredient: Tolnaftate 1% w/w. Also contains Sterilized Talc, Corn Starch.