

LAMISIL - terbinafine hydrochloride spray
Physicians Total Care, Inc.

Drug Facts

Active ingredient

Terbinafine hydrochloride

Purpose

Antifungal

Uses

- cures most jock itch (tinea cruris)
- relieves itching, burning, cracking, and scaling which accompany this condition

Warnings

For external use only

Do Not Use

- on nails or scalp
- in or near the mouth or the eyes
- for vaginal yeast infections

When using this product

do not get into eyes. If contact occurs, rinse eyes thoroughly with water.

Stop use and ask a doctor

if too much irritation occurs or gets worse.

Keep Out of Reach of Children

If swallowed, get medical help or contact a Poison Control
Center right away.

Directions

- adults and children 12 years and over
 - wash the affected area with soap and water and dry completely before applying
 - to open remove clear cap.
 - hold can 4" to 6" from skin. Press and hold to spray a thin layer over affected area
 - spray affected area once a day (morning **or** night) for 1 week or as directed by a doctor
 - release to stop spray
 - wipe excess from spray opening after each use
 - return cap to can

- wash hands after each use
- children under 12 years: ask a doctor

Other information

store at 8° - 25° C (46° - 77° F)

Additional Information

Full Prescription Strength

Continuous Spray Action

Cures Most Jock Itch

For Effective Relief of Itching & Burning

Distr. By:

Novartis Consumer Health, Inc.

Parsippany, NJ 07054-0622 ©2009

Inactive ingredients

Ethanol, polyoxyl 20 cetostearyl ether, propylene glycol, purified water

Questions

call **1-800-452-0051** or visit us at www.lamisilat.com

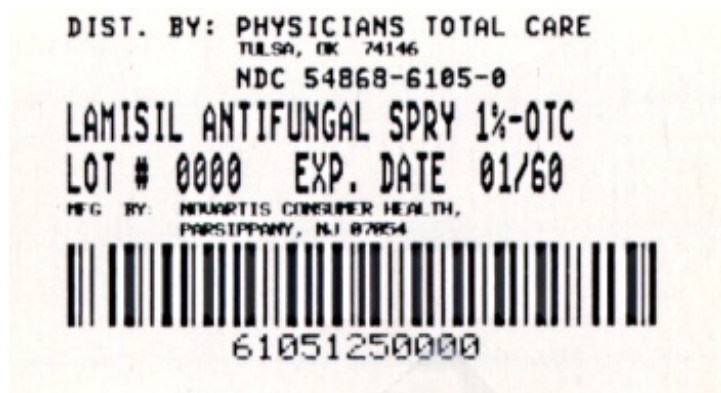
Principal Display

Relabeling of "Additional Barcode" by:

Physicians Total Care, Inc.

Tulsa, OK 74146

NDC 54868-6105-0



LAMISIL

terbinafine hydrochloride spray

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54868-6105(NDC:0067-6293)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
TERBINAFINE HYDROCHLORIDE (UNII: 012C11ZU6G) (TERBINAFINE - UNII:G7RIW8S0XP)	TERBINAFINE HYDROCHLORIDE	1.25 mL in 125 mL

Inactive Ingredients	
Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54868-6105-0	125 mL in 1 BOTTLE, SPRAY		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA021124	04/13/2010	

Labeler - Physicians Total Care, Inc. (194123980)

Establishment

Name	Address	ID/FEI	Business Operations
Physicians Total Care, Inc.		194123980	relabel

Revised: 1/2010

Physicians Total Care, Inc.