TOLNAFTATE - tolnaftate cream
NeoPharm Co., Ltd.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Purpose

Antifungal

Uses

- clinically proven to cure most athlete's foot (tinea pedis) and ringworm (tinea corporis)
- helps prevnet most athlete's foot from recurring when used daily
- effectively soothes and relieves symptoms of athlete's foot, including itching, burning and cracking

Warning

For external use only

When using this product

avoid contact with the eyes

Stop use and ask a doctor if

- irritation occurs
- there is no improvement within 4 weeks

Do not use

on children under 2 years of age except under the advice and supervision of a doctor

Keep out of reach of children

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

Directions

- wash affected area and dry thoroughly
- apply a thin layer over affected area twice daily (morning and night)
- supervise children in the use of this product
- for athlete's foot, pay special attention to spaces between the toes, wear well-fitting ventilated shoes and change shoes and socks at least once daily
- use daily for 4 weeks; if condition persists longer, ask a doctor
- to prevent athlete's foot, apply once of twice daily (morning and/or night)
- this product is not effective on the scalp or nails

Other Information

- store between 2° and 30°C (36° and 86°F)

Inactive ingredients

Carbomer, Cetyl alcohol, Cholesterol, Dibasic sodium phosphate hydrate, Glycerin, Glyceryl monostearate, Light liquid paraffin, Myristoyl/palmitoyl oxostearamide/arachamide MEA, PEG-15 glyceryl stearate, Stearic acid, Water

Principal Display Panel

Tolnaftate

Active Ingredients

Tolnaftate 1%

TOLNAFTATE

tolnaftate cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:51141-0057
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Tolnaftate (UNII: 06KB629TKV) (Tolnaftate - UNII:06KB629TKV)	Tolnaftate	1 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
Alcohol (UNII: 3K9958V90M)	
Glycerin (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
Paraffin (UNII: I9O0E3H2ZE)	
Stearic acid (UNII: 4ELV7Z65AP)	
Water (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:51141-0057-1	1 in 1 BOX		
1		28 g in 1 TUBE		
2	NDC:51141-0057-6	1 in 1 BOX		
2		20 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	08/27/2010	

Labeler - NeoPharm Co., Ltd. (631101883)

Registrant - NeoPharm Co., Ltd. (631101883)

Establishment

Name	Address	ID/FEI	Business Operations
NeoPharm Co., Ltd.		631101883	manufacture

Revised: 8/2010

NeoPharm Co., Ltd.