

CLOTRIMAZOLE - clotrimazole 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

Active Ingredient

Clotrimazole 1%

Purpose

Antifungal

Uses

- cures most athlete's foot, jock itch, and ringworm
- relieves itching, burning, cracking, scaling and discomfort which accompany these conditions

Warnings

Do not use on children under 2 years of age except under the advice and supervision of a doctor

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(for athlete's foot and ringworm) or 2 weeks (for jock itch)
- do not use for diaper rash

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 cover affected area twice daily (morning and night) or as directed by a doctor
- 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 a day
- for athlete's foot and ringworm use daily for 4 weeks, for jock itch use daily for 2 weeks
- if conditions persist longer, ask a doctor
- this product is not effective on the scalp or nails

Other information

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

Inactive ingredients

Benzyl alcohol, Carbomer940, Cetyl alcohol, Glycerin, Glyceryl monostearate, Light liquid paraffin, Myristoyl/palmitoyl oxostearamide/arachamide MEA, PEG-15 glyceryl stearate, Stearic acid, Trolamine, Purified water

Clotrimazole

ANTIFUNGAL

NDC No. 51141-0657-4
Pure-Aid™

CURES & PREVENTS ATHLETE'S FOOT

- Cures Most Athlete's Foot
- Relieves Itching, Burning & Cracking
- Greaseless and Non-Stinging



Compare to the active ingredient of Lotrimin®*



CURES & PREVENTS ATHLETE'S FOOT

CREAM USP 1% ANTIFUNGAL

Clotrimazole

Relieves Itching, Burning & Cracking

CURES & PREVENTS ATHLETE'S FOOT

CREAM USP 1% ANTIFUNGAL

Clotrimazole

Relieves Itching, Burning & Cracking

NET 1 oz (28.3g)

CREAM USP 1% ANTIFUNGAL
Clotrimazole
Relieves Itching, Burning & Cracking


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LOT & EXP.

<p>Drug Facts (continued)</p> <ul style="list-style-type: none"> ■ apply a thin layer over affected area twice daily (morning and night) or as directed by a doctor ■ 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 a day ■ for athlete's foot and ringworm use daily for 4 weeks, for athlete's foot use daily for 2 weeks ■ if conditions persist longer, ask a doctor ■ this product is not effective on the scalp or nails <p>Other Information</p> <ul style="list-style-type: none"> ■ store between 2 and 30°C (36 and 86°F) 	<p>Drug Facts</p> <p>Active Ingredient Clotrimazole 1%.....Antifungal</p> <p>Purpose Antifungal</p> <p>Uses ■ cures most athlete's foot, jock itch, and ringworm ■ relieves itching, burning, cracking, scaling and discomfort which accompany these conditions</p> <p>Warnings Do not use on children under 2 years of age except under the advice and supervision of a doctor For external use only</p> <p>When using this product avoid contact with the eyes</p> <p>Stop use and ask a doctor if ■ irritation occurs ■ there is no improvement within 4 weeks (for athlete's foot and ringworm) or 2 weeks (for jock itch) ■ do not use for diaper rash</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p> <p>Directions ■ wash affected area and dry thoroughly</p>
<p><small>Exclusively distributed by: Karway Product Inc. Compton, CA 90220</small></p> <p><small>This product is not manufactured or distributed by Schering-Plough Healthcare Products, Inc., owner of the registered Trademark Lotrimin®</small></p> <p><small>Trolamine, Purified water</small></p> <p><small>arachamide MEA, PEG-15 glyceryl stearate, Stearic acid, liquid paraffin, Myristoyl / palmitoyl oxostearamide/ Cetyl alcohol, Glycerin, Glyceryl monostearate, Light</small></p> <p><small>inactive ingredients Benzyl alcohol, Carbomer940,</small></p>	

Relieves Itching, Burning & Cracking
Clotrimazole
Pure-Aid™

CLOTRIMAZOLE

clotrimazole cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51141-0657
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Clotrimazole (UNII: G07GZ97H65) (Clotrimazole - UNII:G07GZ97H65)	Clotrimazole	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PARAFFIN (UNII: I9O0E3H2ZE)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51141-0657-1	1 in 1 BOX		
1		28 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	09/02/2010	

Labeler - NeoPharm Co., Ltd. (631101883)

Registrant - NeoPharm Co., Ltd. (631101883)

Establishment

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

