

BIO-SCRIPTIVES EXTREME AF - tolnaftate cream

BioChemics, Inc.

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 Ingredients

Tolnaftate 1%

Purpose

Antifungal

Uses

- Proven clinically effective in the treatment of athlete's foot.
- Relieves itching and burning feet.

Warnings

- Do not use on children under 2 years of age.
- Do not use for diaper rash.
- For external use only.
- Avoid contact with eyes.

Stop use and ask a doctor if

- irritation occurs or if there is no improvement within 4 weeks.

Directions

- Wash the feet and dry thoroughly.
- Apply a thin layer of product to the feet once or twice daily (morning and/or night).
- Supervise children in the use of this product.
- Pay special attention to the spaces between the toes; wear well-fitting, ventilated shoes and change shoes and socks at least once daily.
- Do not use if safety seal is broken.

Inactive Ingredients

Purified Water, Glyceryl Stearate SE, Stearyl Alcohol, Isopropyl Alcohol, Aloe Barbadensis Leaf Juice, Olive Oil, Menthol, Propylene Glycol, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, L-Arginine hydroxide, PEG-40 Hydrogenated Castor Oil, Eucalyptus Globulus, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Althaea Officinalis Extract, Echinacea Angustifolia Extract, Allantoin, Tagetes Erecta Extract, Sodium Chloride, Ascophyllum Nodosum Extract, Xanthan Gum, Azadirachta Indica (Neem) Seed Oil, Methylisothiazolinone

Reference

Distributed by BioChemics dba Bio-Scriptives
99 Rosewood Dr. #260 - Danvers, MA 01923
978-750-0790

Labeling



Drug Facts

Active Ingredients	Purpose
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Uses ■ Proven clinically effective in the treatment of athlete's foot.
 ■ Relieves itching & burning feet.


Warnings

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- Do not use for diaper rash.
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- irritation occurs or if there is no improvement within 4 weeks.

Directions ■ Wash the feet and dry thoroughly.



Drug Facts (continued)

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Keep out of reach of children

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BIO-SCRIPTIVES EXTREME AF			
tolnaftate cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60608-013
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	TOLNAFTATE (UNII: 06KB629TKV) (TOLNAFTATE - UNII:06KB629TKV)	TOLNAFTATE	.56 g in 56.69 g
Inactive Ingredients			
	Ingredient Name	Strength	
	CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L)		
	PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
	XANTHAN GUM (UNII: TTV12P4NEE)		
	WATER (UNII: 059QF0K00R)		
	ARGININE HYDRO CHLORIDE (UNII: F7LTH1E20 Y)		

SODIUM CHLORIDE (UNII: 451W47IQ8X)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
ALLANTOIN (UNII: 344S277G0Z)
ALTHAEA OFFICINALIS ROOT (UNII: TRW2FUF47H)
ECHINACEA ANGUSTIFOLIA LEAF (UNII: FS7G8S6PJ8)
ASCOPHYLLUM NODOSUM (UNII: 168S4EO8YJ)
TAGETES ERECTA FLOWER (UNII: UH5X33P33E)
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)
MENTHOL (UNII: L7T10EP3A)
EUCALYPTUS GLOBULUS LEAF (UNII: S546YLW6E6)
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)
OLIVE OIL (UNII: 6UYK2W1W1E)
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)
AZADIRACHTA INDICA SEED OIL (UNII: 4DKJ9B3K2T)
ISOPROPYL ALCOHOL (UNII: ND2M416302)
MELALEUCA ALTERNIFOLIA LEAF (UNII: G43C57162K)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60608-013-00	56.69 g in 1 BOTTLE, PUMP		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	07/27/2011	

Labeler - BioChemics, Inc. (802946426)

Establishment

Name	Address	ID/FEI	Business Operations
Coastal Products Company		782445688	manufacture

Revised: 7/2011

BioChemics, Inc.