# 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.

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# **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.

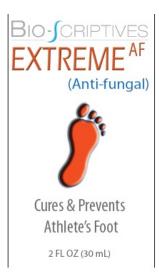
#### **Inactive Ingredients**

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 Hdrogenated 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







# 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: 059QF0KO0R)			
ARGININE HYDRO CHLO RIDE (UNII: F7LTH1E20 Y)			

SODIUM CHLORIDE (UNII: 451W47IQ8X)	
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	
ALLANTO IN (UNII: 344S277G0Z)	
ALTHAEA OFFICINALIS ROOT (UNII: TRW2FUF47H)	
ECHINACEA ANGUSTIFOLIA LEAF (UNII: FS7G8S6PJ8)	
ASCOPHYLLUM NODOSUM (UNII: 168S4EO8YJ)	
TAGETES ERECTA FLOWER (UNII: UH5X33P33E)	
STEARYL ALCOHOL (UNII: 2KR8914H1Y)	
METHYLISOTHIAZOLINONE (UNII: 229 D0 E1QFA)	
MENTHOL (UNII: L7T10 EIP3A)	
EUCALYPTUS GLOBULUS LEAF (UNII: S546 YLW6 E6)	
GLYCERYL MONOSTEARATE (UNII: 230 O U9 XXE4)	
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.