

BARIELLE FUNGUS RX MAXIMUM STRENGTH ANTI-FUNGAL - tolnaftate solution
Fisk Industries

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.

Barielle Fungus Rx Maximum Strength Anti-Fungal Solution

Active ingredient

Active ingredient	Purpose
Tolnaftate 1.0%.....	Antifungal

Uses

- Cures and prevents most athlete's foot (tinea pedis). - Effectively relieves itching, burning, cracking and scaling accompanying the above condition.

Warnings

For external use only

Keep out of reach of children

- In case of accidental ingestion contact a physician, emergency medical care facility or poison control center.

Stop use

- Stop use and ask a physician if rash or irritation occurs.

Do not use

On children under 2 unless directed by a doctor.

Directions

- To prevent athlete's foot, wash the feet and dry thoroughly. - Apply a thin layer of the product to the feet once or twice daily (morning and/or night). - Supervise children in the use of this product. - Pay special attention to spaces between the toes - Wear well-fitting, ventilated shoes, and change shoes and socks at least once daily.

Other information

- You may report a serious adverse event from use of this product to Fisk Industries, Inc. 50 Ramland Road, Orangeburg, NY 10962

Inactive ingredients

Water, PEG-8, Cetearyl Alcohol, Ceteth-20 Phosphate, Decetyl Phosphate, Propylene Glycol, Cocamidopropyl Betaine, Octoxynol-9, Aloe Barbadosensis Leaf Extract, Glyceryl Stearate, Hydroxyethyl Cellulose, Stearyl Alcohol, Imidazolidinyl Urea, Cetyl Alcohol, Methylparaben,

Propylparaben, Triethanolamine.

Purpose

Antifungal

Description

BIORIUS sprl, 2 rue René Descartes B-7000 Mons, Belgium DISTRIBUTED BY FISK INDUSTRIES ORANGEBURG, NY 10962, USA

BARIELLE FUNGUS RX MAXIMUM STRENGTH ANTI-FUNGAL SOLUTION 30 ml / Fl. Oz. (U.S.) e

Directions

Inner Package 1



BIORIUS sprl, 2 rue René Descartes B-7000 Mons, Belgium
DISTRIBUTED BY FISK INDUSTRIES
ORANGEBURG, NY 10962, USA



Drug Facts	
Active ingredient Tolnaftate 1.0%.....	Purpose Antifungal
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Peel Here For More Drug Facts

Inner Package 2

Back Side (peel back)

Directions ■ To prevent athlete's foot, wash the feet and dry thoroughly. ■ Apply a thin layer of the product to the feet once or twice daily (morning and/or night). ■ Supervise children in the use of this product. ■ Pay special attention to spaces between the toes ■ Wear well-fitting, ventilated shoes, and change shoes and socks at least once daily.

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Stop Peeling

BARIELLE FUNGUS RX MAXIMUM STRENGTH ANTI-FUNGAL

tolnaftate solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42593-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TOLNAFTATE (UNII: 06KB629TKV) (TOLNAFTATE - UNII:06KB629TKV)	TOLNAFTATE	1.0 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)
CETETH-20 (UNII: I835H2IHHX)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)
OCTOXYNOL 9 (UNII: 7JPC6Y25QS)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)
STEARYL ALCOHOL (UNII: 2KR89I4HIY)
IMIDUREA (UNII: M629807ATL)
CETYL ALCOHOL (UNII: 936JST6JCN)
METHYLPARABEN (UNII: A2I8C7HI9T)
PROPYLPARABEN (UNII: Z8IX2SC1OH)
TROLAMINE (UNII: 9O3K93S3TK)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42593-002-30	1 in 1 PACKAGE		
1		30 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	01/01/2012	

Labeler - Fisk Industries (067633180)

Establishment

Name	Address	ID/FEI	Business Operations
Private Label Partners, Inc.		046033481	manufacture

Revised: 2/2012

Fisk Industries