

**BARIELLE PROFESSIONAL MAXIMUM STRENGTH FUNGUS RX ANTIFUNGAL PRO -
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 Professional Maximum Strength Fungus Rx Antifungal Solution PRO

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 Barbadensis Leaf Extract, Glyceryl Stearate,

Hydroxyethyl Cellulose, Stearyl Alcohol, Imidazolidinyl Urea, Cetyl Alcohol, Methylparaben, Propylparaben, Triethanolamine.

Purpose

Antifungal

Description

NDC66425-006-20 117710

BIORIUS sprl, 2 rue René Descartes B-7000 Mons, Belgium DISTRIBUTED BY FISK INDUSTRIES ORANGEBURG, NY 10962, USA Made in U.S.A. LOT # 0326BR 7 20817 30326 1 PART # 0326FC

BARIELLE PROFESSIONAL MAXIMUM STRENGTH FUNGUS RX ANTIFUNGAL SOLUTION PRO 30 ml / Fl. Oz. (U.S.) e

Directions

NDC66425-006-20 117710 Drug Facts

FUNGUS RX PUISSANCE MAXIMUM SOLUTION ANTIFONGIQUE TUE LES GERMES QUI CAUSENT LES INFECTIONS FONGIQUES PRO 30 ml / Fl. Oz. (U.S.) e

BARIELLE PROFESSIONAL MAXIMUM STRENGTH FUNGUS RX ANTIFUNGAL SOLUTION KILLS GERMS THAT CAN CAUSE FUNGAL INFECTIONS PRO 30 ml / Fl. Oz. (U.S.) e BIORIUS sprl, 2 rue René Descartes B-7000 Mons, Belgium DISTRIBUTED BY FISK INDUSTRIES ORANGEBURG, NY 10962, USA Made in U.S.A. LOT #

FUNGUS RX MAXIMA POTENCIA SOLUCION ANTIFUNGICA MATA LOS GERMENES QUE PUEDEN CAUSAR INFECCIONES FUNGICAS PRO 30 ml / Fl. Oz. (U.S.) e PART # 0326FC

Inner Package 1

Drug Facts	
Active ingredient Tolnaftate 1.0%.....	Purpose 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 ■ In case of accidental ingestion contact a physician, emergency medical care facility or poison control center. ■ Stop use and ask a physician if rash or irritation occurs.	
Do not use On children under 2 unless directed by a doctor.	

Peel Here For More Drug Facts

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



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.

Other information

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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 Barbadensis Leaf Extract, Glyceryl
Stearate, Hydroxyethyl Cellulose, Stearyl
Alcohol, Imidazolidinyl Urea, Cetyl Alcohol,
Methylparaben, Propylparaben, Triethanolamine.

Stop Peeling

Outer Package 1

NDC66425-006-20

117710

Drug Facts

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

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

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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 Barbadensis Leaf Extract, Glyceryl Stearate, Hydroxyethyl Cellulose, Stearyl Alcohol, Imidazolidinyl Urea, Cetyl Alcohol, Methylparaben, Propylparaben, Triethanolamine.

FUNGUS RX
PUISSANCE
MAXIMUM

SOLUTION ANTIFONGIQUE
TUE LES GERMES QUI CAUSENT
LES INFECTIONS FONGIQUES

PRO

30 ml / 1 Fl. Oz. (U.S.) e

Outer Package 3



BARIELLE®

PROFESSIONAL

MAXIMUM STRENGTH

FUNGUS RX

**ANTIFUNGAL SOLUTION
KILLS GERMS THAT CAN CAUSE
FUNGAL INFECTIONS**

PRO

30 ml / 1 Fl. Oz. (U.S.) e

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

Made in U.S.A. / Fabriqué aux É-U
Fabricado en EE.UU.



LOT #

Outer Package 4

FUNGUS RX
**MÁXIMA
POTENCIA**

SOLUCIÓN ANTIFÚNGICA
MATA LOS GÉRMENES QUE PUEDEN
CAUSAR INFECCIONES FÚNGICAS

PRO

30 ml / 1 Fl. Oz. (U.S.) e

PART #
0326FC

BARIELLE PROFESSIONAL MAXIMUM STRENGTH FUNGUS RX ANTIFUNGAL PRO

tolnaftate solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42593-001
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: 5OCF3011KX)	
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:42593-001-30	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