## INITIAL DRUG LISTING - HERMON ATHLETES FOOT 1% TOLNAFTATE CREAMtolnaftate 1% cream Beautivity LLC

\_\_\_\_\_

## Initial Drug Listing - Hermon Athlete's foot 1% tolnaftate cream

Tolnaftate 1%

### **Antifungal**

- cures most athlete's foot (tinea pedis)
- cures most jock itch (tinea crurs) and ringworm(tinea corporis)
- relieves itching, burning, cracking and scaling which accompany these conditions

#### FOR EXTERNAL USE ONLY

- on nails or scalp
- in or near themouth or eyes
- for vaginal yeast infections

do not get into eyes. If eye contact occurs, rinse thoroughly with water

if too much irritationo ccurs or gets worse

If swallowed, call a poison control centre or get medical help right away.

- adults and children 12 years and over
- use the tip of the cap to break the seal and open the tube
- wash the affected skin with soap and water and dry completely before applying
- for athlete's foot wear well-fitting, ventilated shoes. Change shoes and socks at least once daily
- between the toesonly: apply twice a day(morning and night) for 1week or as directed by a doctor
- on the bottomor sides of the foot: apply twice a day(morningand night)for 2 weeks or as directed by a doctor
- for jock itch and ringworm: apply once a day(morning or night) for 1 week or as directed by adoctor
- wash hands after each use
- children under 12 years: ask a doctor
- Do not use if seal on tube is broken or is not visible.
- Store at 68-77°F(20-25°C)

Allantoin, Glycerin, Propylene Glycol, PCA Dimethicone, Ethylparaben, Glyceryl Stearate, Primary Alcohol, Ethoxylate, Alumen, Sodium Acrylate/Sodium, Acryloyldimethyl Taurate Copolymer, Isohexadecane, Polysorbate 80, Aloe Barbadensis Leaf Juice

service@hermonhealth.com



# ATHLETE'S FOOT

CREAM

## PRESCRIPTION STRENGTH

RELIEVES ITCHING BURNING & CRACKING

# CLINICALLY

TOLNAFTATE 1% ANTIFUNGAL

NET WT: **60 g (2 oz)** 

## Drug Facts

#### Active ingredient

Purpose

Tolnaftate 1%.....

....Antifungal

Uses ■ cures most athlete's foot (tinea pedis)
■ cures most jock itch (tinea crurs) and ringworm (tinea corporis) ■ relieves itching, burning, cracking and scaling which accompany these conditions

#### Warnings

#### FOR EXTERNAL USE ONLY.

**DO NOT USE** ■ on nails or scalp ■ in or near the mouth or eyes ■ for vaginal yeast infections

WHEN USING THIS PRODUCT, do not get into eyes. If eye contact occurs, rinse thoroughly with water.

**STOP USE AND ASK A DOCTOR** if too much irritation occurs or gets worse

**KEEP OUT OF REACH OF CHILDREN.** If swallowed, call a poison control centre or get medical help right away.

#### Directions

■ adults and children 12 years and over ■ use the tip of the cap to break the seal and open the tube ■ wash the affected skin with soap and water and dry completely before applying ■ for athlete's foot wear well-fitting, ventilated shoes. Change shoes and socks at least once daily. ■ between the toes only: apply twice a day (morning and night) for 1 week or as directed by a doctor ■ on the bottom or sides of the foot: apply twice a day (morning and night) for 2 weeks or as directed by a doctor ■ for jock itch and ringworm: apply once a day (morning or night) for 1 week or as directed by a doctor ■ wash hands after each use ■ children

#### Other information

under 12 years: ask a doctor

■ Do not use if seal on tube is broken or is not visible. ■ Store at 68-77°F (20-25°C)

#### Inactive ingredients

Allantoin, Glycerin, Propylene Glycol, PCA Dimethicone, Ethylparaben, Glyceryl Stearate, Primary Alcohol Ethoxylate, Alumen, Sodium Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Isohexadecane, Polysorbate 80, Aloe Barbadensis Leaf Juice

Questions? service@hermonhealth.com

# INITIAL DRUG LISTING - HERMON ATHLETES FOOT 1% TOLNAFTATE CREAM

tolnaftate 1% cream

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:85398-017

**Route of Administration** 

**TOPICAL** 

Active Ingredient/Active Moiety
Ingradient Name

TOLNAFTATE (UNII: 06KB629TKV) (TOLNAFTATE - UNII:06KB629TKV) TOLNAFTATE 0.6 g in 60 g

**Basis of Strength** 

Strength

I	1
Inactive	<b>Ingredients</b>
	9

ETHYLPARABEN (UNII: 14255EXE39)

inactive ingredients			
Ingredient Name	Strength		
ALOE BARBADENSIS LEAF JUICE (UNII: RUE8E6T4NB)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
GLYCERYL STEARATE (UNII: 2300U9XXE4)			
SODIUM ACRYLATE/SODIUM ACRYLOYLDIMETHYLTAURATE COPOLYMER (4000000 MW) (UNII: 1DXE3F3OZX)			
ALCOHOL (UNII: 3K9958V90M)			
POTASSIUM ALUM (UNII: 1L24V9R23S)			
GLYCERIN (UNII: PDC6A3C0OX)			
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (45000 MPA.S AT 1%) (UNII: 86FQE96TZ4)			
POLYSORBATE 80 (UNII: 6OZP39ZG8H)			
ALLANTOIN (UNII: 344S277G0Z)			
ISOHEXADECANE (UNII: 918X1OUF1E)			
DIMETHICONE 6 (UNII: RB8V8W9FQN)			

Packaging						
# Item Code	Package Description	Marketing Start Date	Marketing End Date			
NDC:85398-017-	60 g in 1 CARTON; Type 0: Not a Combination Product	10/31/2025				
NDC:85398-017-	57 g in 1 TUBE; Type 0: Not a Combination Product	10/31/2025				

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M005	10/31/2025	

## Labeler - Beautivity LLC (096573788)

## Registrant - Beautivity LLC (096573788)

Revised: 10/2025 **Beautivity LLC**