

**SKIN PROTECTOR WITH BREATHABLE BARRIER- miconazole nitrate cream
DIVERSIFIED MANUFACTURING CORP**

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.

ACTIVE INGREDIENT

MICONAZOLE NITRATE 2%

PURPOSE

ANTIFUNGAL

USES

FOR THE TREATMENT AND PREVENTION OF:

- ATHLETE'S FOOT
- JOCK ITCH
- RINGWORM

RELIEVES ITCHING, SCALING, CRACKING AND DISCOMFORT ASSOCIATED WITH THESE CONDITIONS.

WARNINGS

FOR EXTERNAL USE ONLY.

AVOID CONTACT WITH EYES. IN CASE OF CONTACT, RINSE THOROUGHLY WITH WATER.

STOP USE AND ASK A DOCTOR IF:

- IRRITATION OCCURS
- CONDITION WORSENS OR DOES NOT IMPROVE WITHIN 2 WEEKS FOR JOCK ITCH, OR WITHIN 4 WEEKS FOR ATHLETE'S FOOT AND RINGWORM.

KEEP OUT OF REACH OF CHILDREN. IN CASE OF ACCIDENTAL INGESTION CONTACT A PHYSICIAN OR POISON CONTROL CENTER IMMEDIATELY.

DIRECTIONS

CLEANSE AFFECTED AREA AND DRY THOROUGHLY. APPLY A THIN LAYER TO AFFECTED AREA TWICE DAILY OR AS DIRECTED BY A PHYSICIAN.

- FOR JOCK ITCH USE DAILY FOR TWO WEEKS.
- FOR ATHLETE'S FOOT AND RINGWORM USE DAILY FOR FOUR WEEKS.

OTHER INFORMATION

- THIS PRODUCT IS NOT EFFECTIVE ON THE SCALP OR NAILS.
- STORE AT ROOM TEMPERATURE 59° - 86°F (15° - 30°C).

INACTIVE INGREDIENTS

CAPRYLIC/CAPRIC TRIGLYCERIDE, CETEARETH-20, CETEARYL ALCOHOL, IMIDIAZOLIDINYL UREA, DIMETHICONE, DISODIUM EDTA, GLYCERYL STEARATE, METHYLPARABEN, PEG-40 CASTOR OIL, PEG-100 STEARATE, PETROLATUM, PROPYLENE GLYCOL, PROPYLPARABEN, STEARIC ACID, WATER, XANTHAN GUM.

QUESTIONS?

CALL 877.314.2554

DERMATOLOGIST TESTED

Antifungal Skin Protectant with Breathable Barrier

Treats athlete's foot, jock itch and ringworm

Contains 2% Miconazole Nitrate

embrace

NET WT. 6 OZ.

Compliance PRODUCTS
Quality by Experience/Excellence by Design

Drug Facts	
Active Ingredient	Purpose
Miconazole Nitrate 2%	Antifungal
Uses	
For the treatment and prevention of most: ■ athlete's foot ■ jock itch ■ ringworm	
Relieves itching, scaling, cracking and discomfort associated with these conditions.	
Warnings	
For external use only.	
Avoid contact with eyes. In case of contact, flush thoroughly with water.	
Stop use and ask a doctor if: ■ irritation occurs ■ condition worsens or does not improve within 2 weeks for jock itch, or within 4 weeks for athlete's foot and ringworm.	
Keep out of reach of children. In case of accidental ingestion contact a physician or poison control center immediately.	
Directions	
Cleanse affected area and dry thoroughly. Apply a thin layer to affected area twice daily or as directed by a physician. ■ For jock itch use daily for two weeks. ■ For athlete's foot and ringworm use daily for four weeks.	
Other information ■ This product is not effective on the scalp or nails. ■ Store at room temperature 59° - 86°F (15° - 30°C).	
Inactive ingredients Caprylic/Capric Triglyceride, Ceteareth-20, Cetearyl Alcohol, Imidazolidinyl Urea, Dimethicone, Disodium EDTA, Glycerol Stearate, Methylparaben, PEG-40 Castor Oil, PEG-100 Stearate, Petrolatum, Propylene Glycol, Propylparaben, Stearic Acid, Water, Xanthan Gum.	
Questions? Call 877.314.2554	

INTERNATIONAL direct
www.internationaldirect.com Chicago, IL 60611
Reorder # 600-BCA4N1
8 14125 01082 6

SKIN PROTECTOR WITH BREATHABLE BARRIER

miconazole nitrate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62172-202
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength	
MICONAZOLE NITRATE (UNII: VW4HICYW1K) (MICONAZOLE - UNII:7NNO0D7S5M)		MICONAZOLE NITRATE	2 g in 100 g	
Inactive Ingredients				
Ingredient Name			Strength	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)				
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)				
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)				
IMIDUREA (UNII: M629807ATL)				
DIMETHICONE (UNII: 92RU3N3Y1O)				
EDETATE DISODIUM (UNII: 7FLD91C86K)				
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)				
METHYL PARABEN (UNII: A2I8C7HI9T)				
PEG-40 CASTOR OIL (UNII: 4ERD2076EF)				
PEG-100 STEARATE (UNII: YD01N1999R)				
PETROLATUM (UNII: 4T6H12BN9U)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
PROPYL PARABEN (UNII: Z8IX2SC1OH)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
WATER (UNII: 059QF0KO0R)				
XANTHAN GUM (UNII: TTV12P4NEE)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62172-202-16	180 g in 1 TUBE; Type 0: Not a Combination Product	05/04/2016	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part333C	05/04/2016		

Labeler - DIVERSIFIED MANUFACTURING CORP (185073996)

Establishment

Name	Address	ID/FEI	Business Operations
DIVERSIFIED MANUFACTURING CORP		185073996	manufacture(62172-202)

Revised: 2/2019

DIVERSIFIED MANUFACTURING CORP