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

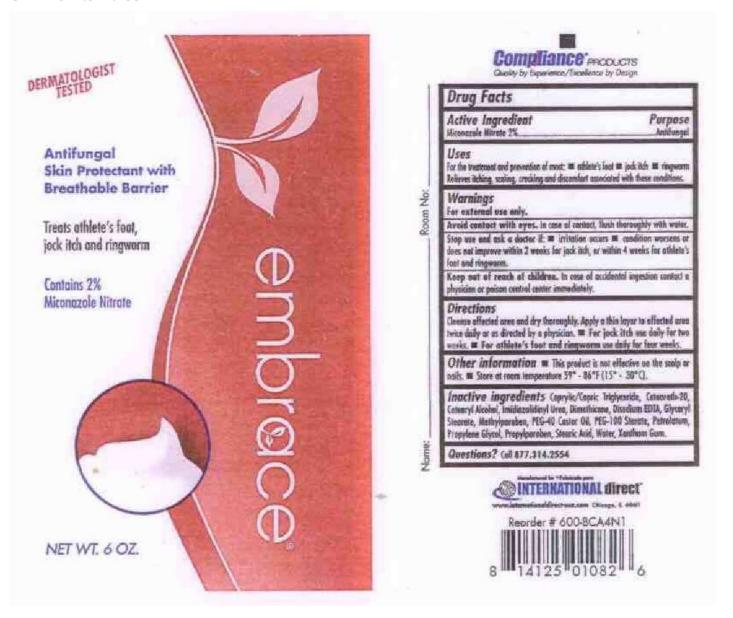
- THIS PRODUCT IS NOT EFFECTIVE ON THE SCALP OR NAILS.
- STORE AT ROOM TEMPERATURE 59° 86°F (15° 30°C).

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



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
MICO NAZO LE NITRATE (UNII: VW4H1CYW1K) (MICONAZO LE - UNII:7NNO 0 D7S5M)	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)		
DIMETHICO NE (UNII: 92RU3N3Y1O)		
EDETATE DISO DIUM (UNII: 7FLD9 1C86K)		
GLYCERYL MONOSTEARATE (UNII: 230 O U9 XXE4)		
METHYLPARABEN (UNII: A2I8C7HI9T)		
PEG-40 CASTOR OIL (UNII: 4ERD2076EF)		
PEG-100 STEARATE (UNII: YD01N1999R)		
PETROLATUM (UNII: 4T6H12BN9U)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
PROPYLPARABEN (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