NOVANA ANTIFUNGAL BARRIER WITH MICONAZOLE - miconazole nitrate cream
Novana Medical, LLC

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.

Drug Facts

Active ingredient	**Purpose**
Miconazole Nitrate 2%.....	Antifungal

Indications •For effective treatment of athlete's foot (dermatophytosis), jock itch (tinea cruris), and ringworm (tinea corporis). • For the relief of burning, redness, irritation, discomfort, itching, scaling, and cracking.

Warnings

For external use only.

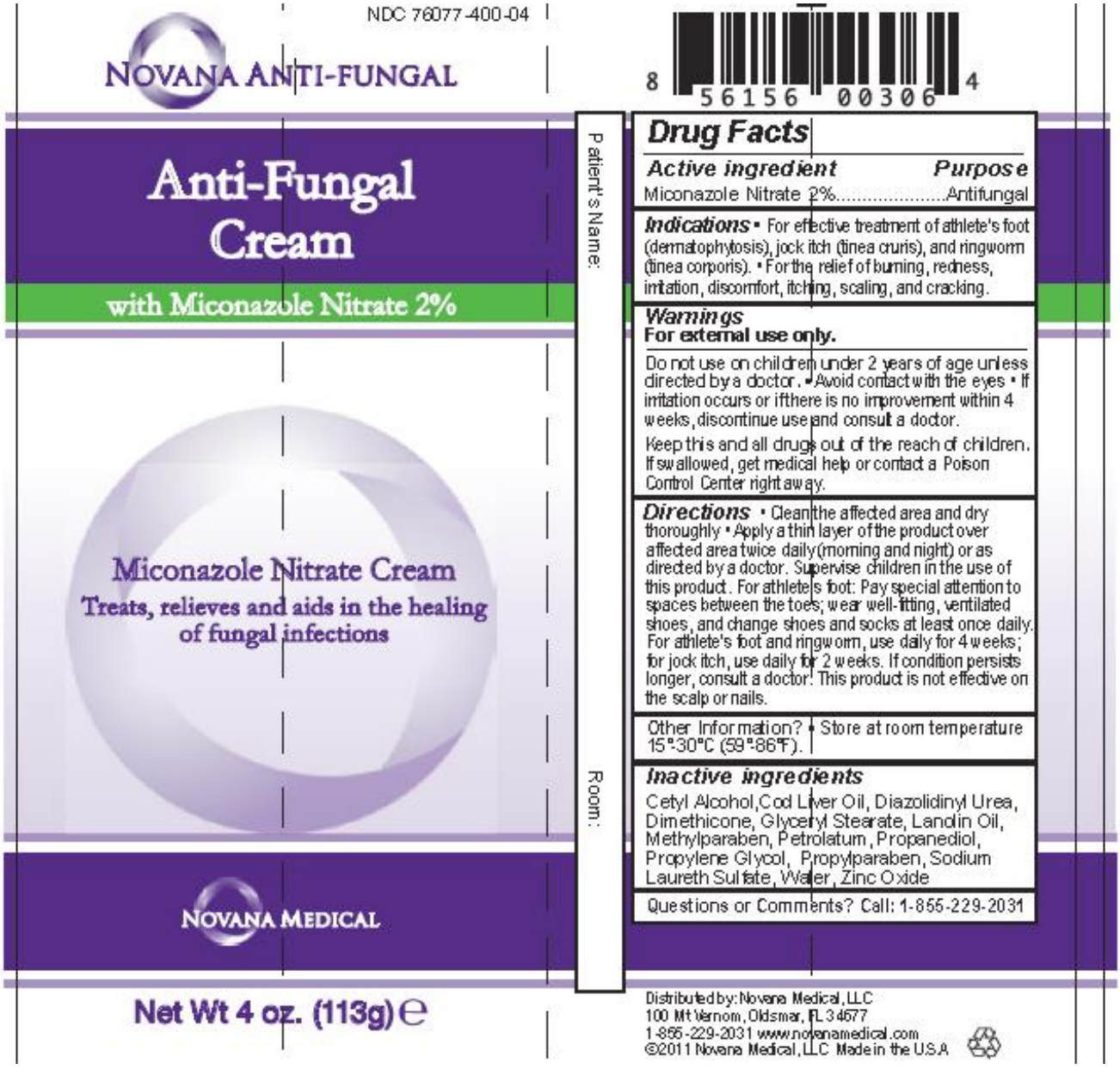
Do not use on children under 2 years of age unless directed by a doctor. • Avoid contact with the eyes • If irritation occurs or if there is no improvement within 4 weeks, discontinue use and consult a doctor.

Keep this and all drugs out of the reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions • Clean the affected area and dry thoroughly • Apply a thin layer of the product over affected area twice daily (morning and night) or as directed by a doctor. Supervise children in the use of this product. For athlete's foot: Pay special attention to spaces between the toes; wear well-fitting, ventilated shoes, and change shoes and socks at least once daily. For athlete's foot and ringworm, use daily for 4 weeks; for jock itch, use daily for 2 weeks. If condition persists longer, consult a doctor. This product is not effective on the scalp or nails.

Use Daily for 2 weeks.
If condition persists, consult a doctor. This product is not effective on scalp or nails.

Inactive ingredients
Cetyl Alcohol,Cod Liver Oil, Diazolidinyl Urea, Dimethicone, Glyceryl Stearate, Lanolin Oil, Methylparaben, Petrolatum, Propanediol, Propylene Glycol, Propylparaben, Sodium Laureth Sulfate, Water, Zinc Oxide



NOVANA ANTIFUNGAL BARRIER WITH MICONAZOLE

miconazole nitrate cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:76077-400
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Miconazole Nitrate (UNII: VW4H1CYW1K) (Miconazole - UNII:7NNO0D7S5M)	Miconazole Nitrate	.02 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Cetyl Alcohol (UNII: 936JST6JCN)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
Petrolatum (UNII: 4T6H12BN9U)	
Lanolin (UNII: 7EV65EAW6H)	
Cod Liver Oil (UNII: BBL281NWFG)	
Propanediol (UNII: 5965N8W85T)	
Sodium Laureth Sulfate (UNII: BPV390UAP0)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Diazolidinyl Urea (UNII: H5RIZ3MPW4)	
Methylparaben (UNII: A2I8C7HI9T)	
Propylparaben (UNII: Z8IX2SC1OH)	
Zinc Oxide (UNII: SOI2LOH54Z)	
Dimethicone (UNII: 92RU3N3Y1O)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76077-400-04	120 mL in 1 TUBE		
2	NDC:76077-400-07	210 mL in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	04/04/2012	

Labeler - Novana Medical, LLC (964916600)

Registrant - O.L. PRODUCTS, INC. (961405883)

Establishment

Name	Address	ID/FEI	Business Operations
Novana Medical, LLC		964916600	label, manufacture

Revised: 4/2012 Novana Medical, LLC