MICONOLE- miconazole nitrate cream
Option Labs

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.

Miconole

Drug Facts

Miconazole Nitrate 2%

Aloe Vera Polysaccharide 1%

Purpose

Antifungal

Other ingredients:

Allantoin, Cetyl Alcohol, Glycerin, Glyceryl Monostearate, Isopropyl Myristate, Methylparaben, Polysorbate 80, Propylene Glycol, Propylparaben, Purified Water, Sodium Hydroxide, Stearic Acid, Fragrance

Uses

for the treatment of

- athletes foot (tinea pedis)
- jock itch (tinea cruris)
- ringworm (tinea corporis)
- superficial skin infections caused by yeast (candida albicans)

Warnings

for external use only

- do not use on children under 2 years of age unless directed by a doctor
- avoid contact with eyes
- If irritation occurs or if there is no improvement within 2 weeks, discontinue use and see a doctor

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- wash 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 ringworm use daily for 4 weeks, if condition persists longer, consult a doctor
- this product is not effective on the scalp or nails.

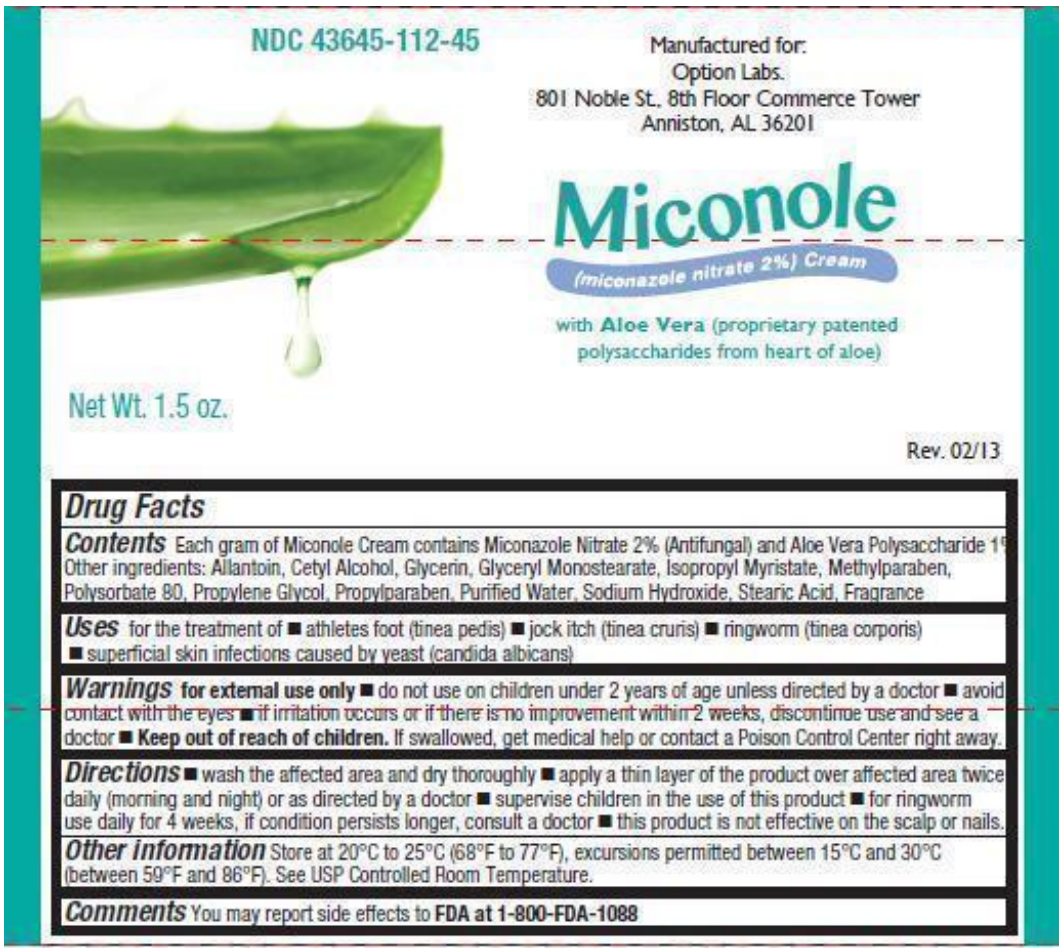
Other Information

Store at 20°C - 25°C (68°F - 77°F), excursions permitted between 15°C and 30°C (between 59°F and 86°F). See USP Controlled Room Temperature.

Comments

You may report side effects to **FDA at 1-800-FDA-1088**

PRINCIPAL DISPLAY PANEL



NDC 43645-112-45

Manufactured for:

Option Labs.

801 Noble St., 8th Floor Commerce Tower

Anniston, AL 36201

Miconole

(miconazole nitrate 2%) Cream

with **Aloe Vera** (proprietary patented

polysaccharides from heart of aloe)

Net Wt. 1.5 oz.

Rev. 02/13

MICONOLE

miconazole nitrate cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:43645-112
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MICONAZOLE NITRATE (UNII: VW4H1CYW1K) (MICONAZOLE - UNII:7NNO0D7S5M)	MICONAZOLE NITRATE	20 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ALLANTOIN (UNII: 344S277G0Z)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:43645-112-45	1 in 1 CARTON		
1		42.5 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	10/15/2013	

Labeler - Option Labs (078380329)

Registrant - Option Labs (078380329)

Revised: 8/2013 Option Labs