MICONAZOLE- miconazole cream
Kinray, Inc.

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.

Antifungal

Active Ingredient

Miconazole Nitrate 2%

Warnings

For External Use Only

Do not use

- on children under 2 years of age unless directed by a doctor.
- for diaper rash

When using this product

- avoid contact with eyes

Stop use and ask a doctor if

- irritation occurs
- there is no improvementwithin 2 weeks when used for the treatment of jock itch
- there is no improvementwithin 4 weeks when used for athletes foot or ringworm

Uses

- For treatment of most athlete's foot (tinea pedis), jock itch (tinea crusis), Ringworm (tinea corporis).
- Relieves itching, scaling, cracking, burning, redness, soreness, irritation discomfort and chafing associated with jock itch or itching burning feet

Indications and Usage

- Supervise children in the use of this product.

Other information.

Store at room temperature

Directions

- Clean the affected area and dry thoroughly. Apply a thin layer of cream 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 toes: wear well-fitting, ventilated shoes, and change shoes and socks at least once daily.
- Foe 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 scalp or nails.

Inactive Ingredients

Inactive Ingredients: Cetomacrogol 1000, cetostearyl alcohol, chlorocresol, liquid paraffin, propylene glycol, purified water, white soft paraffin.

Keep Out of Reach of Children

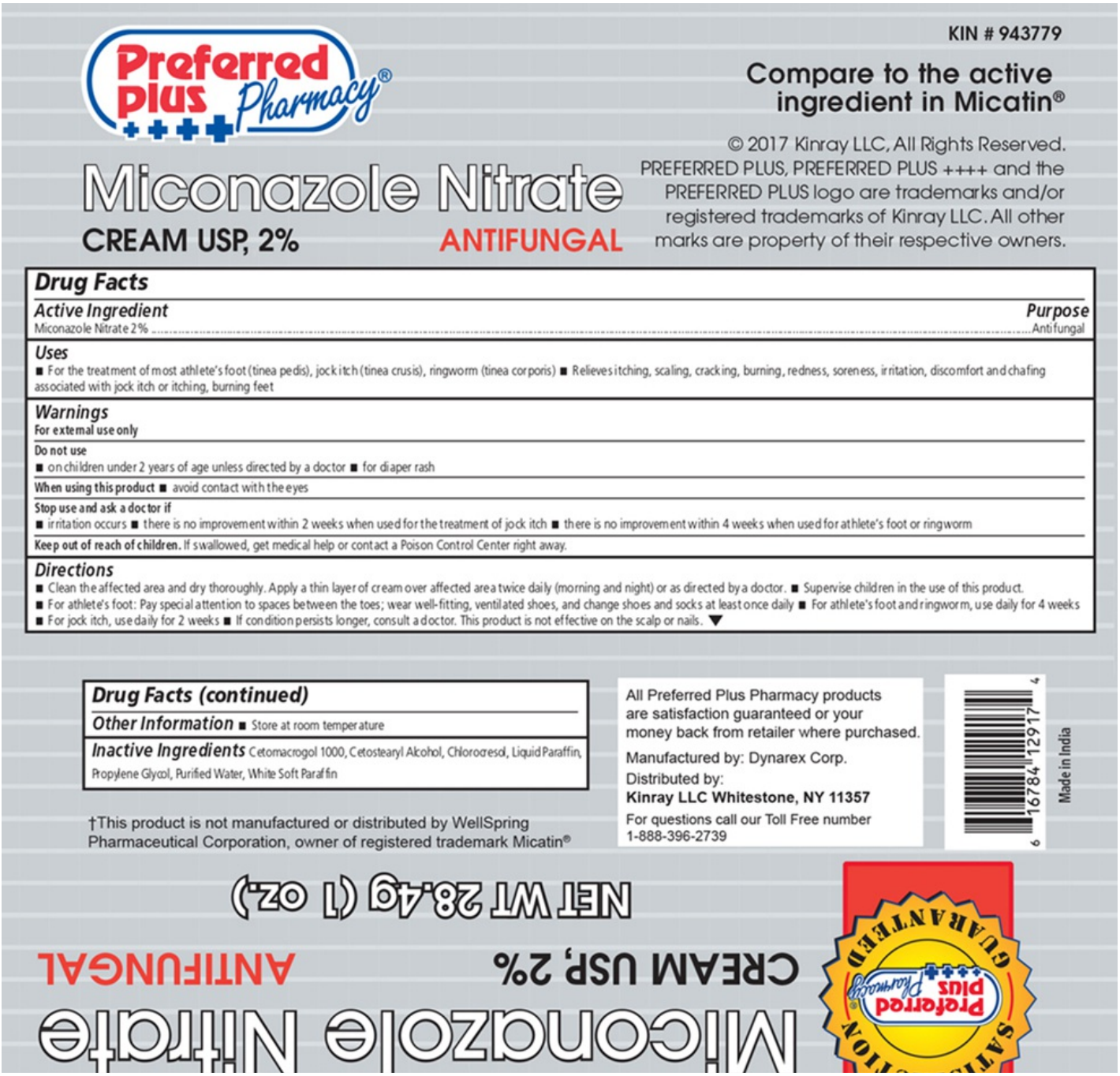
- **KEEP OUT OF REACH OF CHILDREN**
- If swallowed get medical help or contact a Poison Control Center right away

Principal Display Panel

Preferred Plus Pharmacy

Miconazole Nitrate Cream USP 2%

KR Miconazole.jpg



MICONAZOLE

miconazole cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:61715-050
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**
CETETH-20 (UNII: I835H2IHHX)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CHLOROCRESOL (UNII: 36W53O7109)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
MINERAL OIL (UNII: T5L8T28FGP)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**

1	NDC:61715-050-01	28.4 g in 1 TUBE; Type 0: Not a Combination Product	03/22/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	03/21/2013	

Labeler - Kinray, Inc. (012574513)

Registrant - Dynarex Corporation (008124539)

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