MYCOZYL AP- miconazole nitrate powder
PureTek Corporation

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.

Mycozyl AP

Active ingredient

Miconazole Nitrate 2.0%

Purpose

Antifungal

Uses

- for the treatment of most athlete's foot (tinea pedis), jock itch (tinea cruris), ringworm (tinea corporis)
- relieves itching, scaling, cracking, burning, redness, soreness, irritation, discomfort and chafing associated with jock itch

For external use only.

Do not use on

■ children under 2 years of age unless directed by a doctor

When using this product

- do not get into eyes

Stop use and ask a doctor if

- for athlete's foot and ringworm - irritation occurs or there is no improvement within 4 weeks
- for jock itch - irritation occurs or there is no improvement within 2 weeks

Keep out of 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.

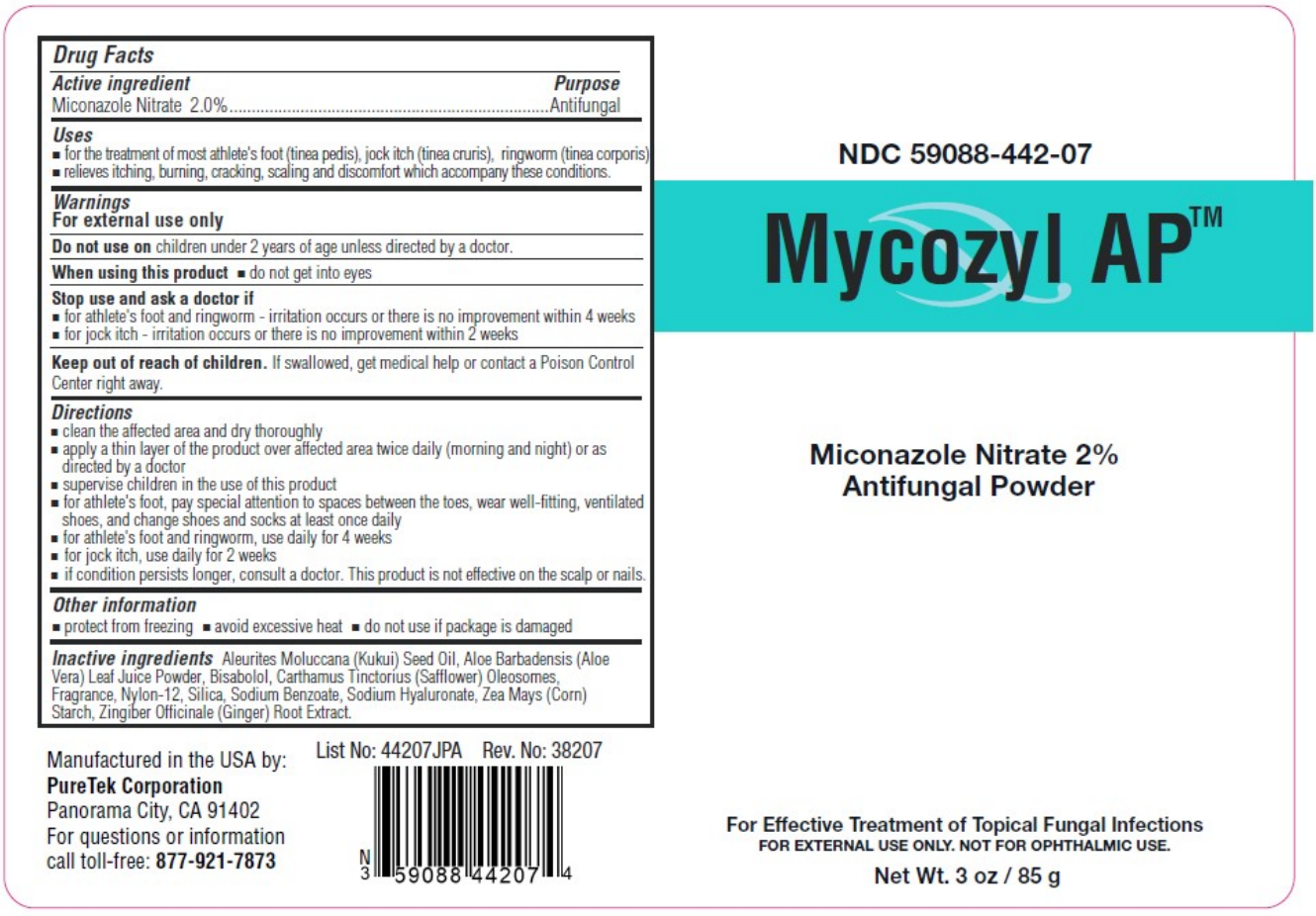
Other information

■ protect from freezing ■ avoid excessive heat ■ do not use if package is damaged

Inactive ingredients

Aleurites Moluccana (Kukui) Seed Oil, Aloe Barbadensis (Aloe Vera) Leaf Juice Powder, Bisabolol, Carthamus Tinctorius (Safflower) Oleosomes, Fragrance, Nylon-12, Silica, Sodium Benzoate, Sodium Hyaluronate, Zea Mays (Corn) Starch, Zingiber Officinale (Ginger) Root Extract.

Mycozyl Antifungal Powder



MYCOZYL AP

miconazole nitrate powder

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:59088-442
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MICONAZOLE NITRATE (UNII: VW4H1CYW1K) (MICONAZOLE - UNII:7NNO0D7S5M)	MICONAZOLE NITRATE	2 g in 85 g

Inactive Ingredients	
Ingredient Name	**Strength**
LEVOMENOL (UNII: 24WE03BX2T)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
STARCH, CORN (UNII: O8232NY3SJ)	
GINGER (UNII: C5529G5JPQ)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
NYLON-12 (UNII: 446U8J075B)	
CARTHAMUS TINCTORIUS (SAFFLOWER) OLEOSOMES (UNII: 9S60Q72309)	
KUKUI NUT OIL (UNII: TP11QR7B8R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:59088-442-07	85 g in 1 BOTTLE; Type 0: Not a Combination Product	12/08/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	12/08/2020	

Labeler - PureTek Corporation (785961046)

Establishment

Name	Address	ID/FEI	Business Operations
PureTek Corporation		785961046	manufacture(59088-442) , label(59088-442)