MYCOZYL AP- miconazole nitrate powder
PureTek Corporation

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.

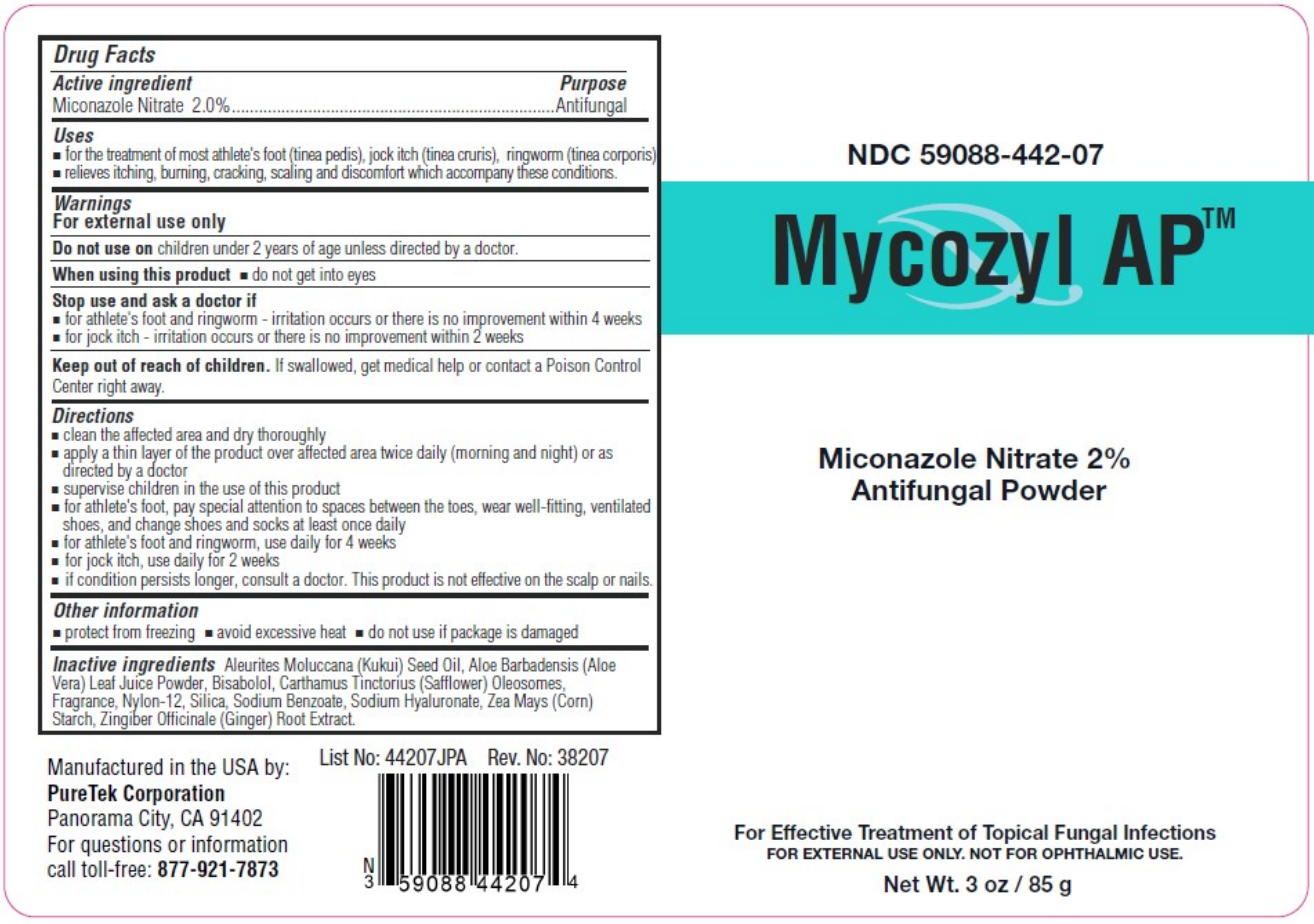
Other information

■ 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 Drug	M005	12/08/2020	

Labeler - PureTek Corporation (785961046)

Establishment

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

Revised: 10/2024 PureTek Corporation