MYCOZYL AC- clotrimazole cream
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 AC™

(Clotrimazole 1% Antifungal Cream)

Drug Facts

Active ingredient

Clotrimazole 1%

Purpose

Antifungal

Uses

■ For the treatment of athlete's foot (tinea pedis), jock itch (tinea cruris), ringworm (tinea corporis).

■ Relieves itching, burning, cracking, scaling, and discomfort which accompanies these conditions.

Warnings

For external use only.

When using this product avoid contact with eyes

Do not use

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

■ for athlete's foot and ringworm - if irritation occurs or if there is no improvement within 4 weeks, discontinue use and consult a doctor

■ for jock itch - if irritation occurs or if there is no improvement in 2 weeks, discontinue use and consult a doctor

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 the 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 under the direction of a medical practitioner

Other information

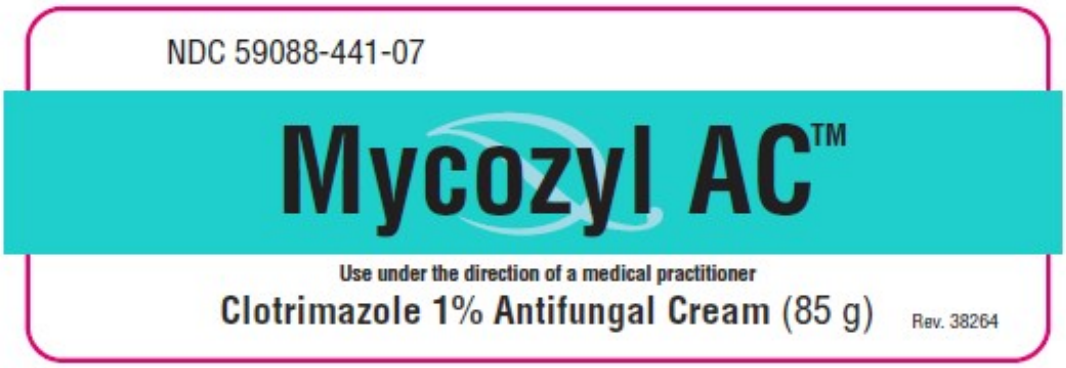
■ Store at 15° - 30°C (59° - 86°F) ■ avoid excessive heat ■ do not use if package is damaged

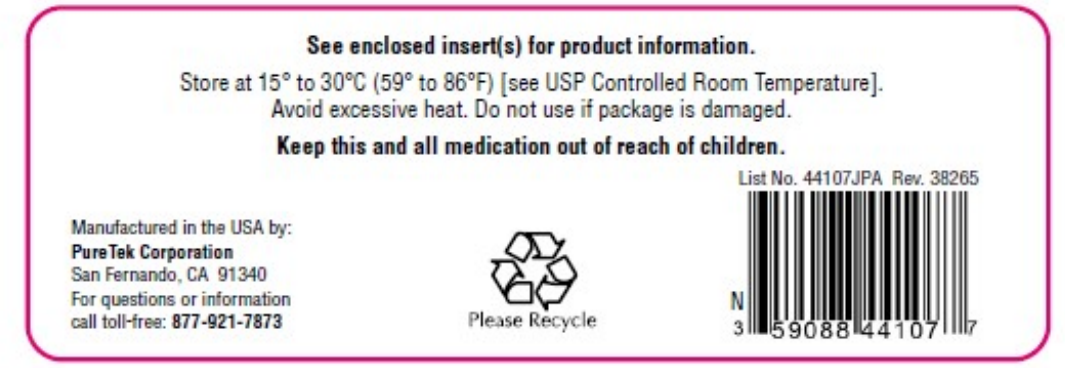
Inactive ingredients

Aqua (Purified Water), Beta-Glucan, Butyrospermum Parkii (Shea) Butter, Caprylyl Glycol, Cetearyl Alcohol, Dimethicone, Disodium EDTA, Ethyl Alcohol, Glycerin, Glyceryl Caprylate, Glyceryl Stearate, Glycine Soja (Soybean) Oil, 1,2-Hexanediol, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Panthenol, PEG-100 Stearate, PEG-40 Stearate PEG-8, Polysorbate 60, Propylene Glycol, Sholigopeptide-1, Simmondsia Chinensis (Jojoba) Seed Oil, Sodium Hydroxide, DL-alpha-tocopheryl acetate

Mycozyl AC ™

Manufactured in the USA by:
PureTek Corporation
San Fernando, CA 91340
For questions or information
call toll-free: **1-877-921-7873**





MYCOZYL AC

clotrimazole cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:59088-441
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CLOTRIMAZOLE (UNII: G07GZ97H65) (CLOTRIMAZOLE - UNII:G07GZ97H65)	CLOTRIMAZOLE	10 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIMETHICONE (UNII: 92RU3N3Y1O)	
TEA TREE OIL (UNII: VIF565UC2G)	
NEPIDERMIN (UNII: TZK30RF92W)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
SOYBEAN OIL (UNII: 241ATL177A)	
PANTHENOL (UNII: WV9CM0O67Z)	
CURDLAN (UNII: 6930DL209R)	
SHEA BUTTER (UNII: K49155WL9Y)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
ALCOHOL (UNII: 3K9958V90M)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL CAPRYLATE (UNII: TM2TZD4G4A)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
PEG-100 STEARATE (UNII: YD01N1999R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
JOJOBA OIL (UNII: 724GKU717M)	
PEG-40 STEARATE (UNII: ECU18C66Q7)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59088-441-07	85 g in 1 TUBE; Type 0: Not a Combination Product	04/06/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	04/06/2021	

Labeler - PureTek Corporation (785961046)

Revised: 1/2023 PureTek Corporation