

MYCOZYL AC- clotrimazole cream
PureTek Corporation

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**

NDC 59088-441-07

Mycozyl AC™

Use under the direction of a medical practitioner

Clotrimazole 1% Antifungal Cream (85 g) Rev. 38264

See enclosed insert(s) for product information.

Store at 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].
Avoid excessive heat. Do not use if package is damaged.

Keep this and all medication out of reach of children.

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San Fernando, CA 91340
For questions or information
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List No. 44107JPA Rev. 38265



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: WW9CM0067Z)	
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 Drug	M005	04/06/2021	

Labeler - PureTek Corporation (785961046)