

MICOTRIN 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.

Micotrin AC™

(Clotrimazole 1% Antifungal Cream)

10/19- Updatng marketing date to 10/25 v2

Drug Facts

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.
- his 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

Micotrin AC™

Manufactured in the USA by:

PureTek Corporation

Panorama City, CA 91402

For questions or information

call toll-free: **877-921-7873**

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List No. 476071AA Rev.38347

NDC 59088-476-07

Micotrin AC™

Clotrimazole 1% Antifungal Cream (85 g)

Use under the direction of a medical practitioner

See enclosed insert(s) for full prescribing information.

Store at 15 to 30°C (59° to 86°F) [see USP Controlled Room Temperature].

Avoid excessive heat.

Keep this and all medication out of reach of children.

List No. 476071AA Rev.38346

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Paretek Corporation
Panorama City, CA 91402
For questions or information
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MICOTRIN AC

clotrimazole cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59088-476
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
WATER (UNII: 059QF0KO0R)	
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)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59088-476-07	85 g in 1 TUBE; Type 0: Not a Combination Product	10/25/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	10/25/2021	

Labeler - PureTek Corporation (785961046)