#### MICOTRIN AC- clotrimazole cream PureTek Corporation

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#### Micotrin AC™

(Clotrimazole 1% Antifungal Cream)

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

#### **Drug Facts**

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#### **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** 

Drug Facts Active ingredient Clotrimazole 1% Antifungal	NDC 59088-476-07		
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 accompany these conditions.	Micotrin AC <sup>™</sup>		
Warnings For external use only.	inteotini, Ae		
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 initiation occurs or if there is no improvement within 4 weeks, discontinue use and consult a doctor • for jock lich - if imitation 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.	Clotrimazole 1% Antifungal Cream (85 g)		
Directions         • Clean the affected area and dry thoroughly.         • Apply a thin layer of the product over affected area twice daily (moming 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 ornalis.	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	See enclosed insert(s) for full prescribing information.		
Inactive ingredients Aqua (Purified Water), Beta-Glucan, Butyrospermum Parking's butking of Butter, Caprylyl Glycol, Cetearyl Alcohol, Dimethicone, Disodium EDTA, Ethyl Alcohol, Glycerin, Glyceryl Caprylate, Glyceryl Stearate, Glycine Soja (Soybean) Oit, 12-Hexanediol, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Panthenol, PEG-100 Stearate, PEG-40 Stearate, PEG-8, Polysorbate 60, Propylene Glycol, Sh-oligopeptide-1, Simmond sia Chinensis (Jojoba) Seed Oil, Sodium Hydroxide, DL-Alpha- Tocopheryl Acetate.	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. Manufactured in the USA by: PureTek Corporation Parorama CBy, CA 91402 For questions or information call toll-free: 877-921-7873 Please Recycle Name State Stat		

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# **MICOTRIN AC**

clotrimazole cream

Product Information						
Product Type	HUMAN OTC DRUG	Item Code (Source)		NDC:59	DC:59088-476	
Route of Administration	TOPICAL					
Active Ingredient/Active	Moiety					
Ingr	edient Name	Basis of Stren		nath	Stron	
ingre			Dasis of Stre	ingun	Stren	gth
CLOTRIMAZOLE (UNII: G07GZ97F		G07GZ97H65)	CLOTRIMAZOLE	-	10 mg i	-
CLOTRIMAZOLE (UNII: G07GZ97H		G07GZ97H65)		-		-
-	i65) (CLOTRIMAZOLE - UNII:	G07GZ97H65)			10 mg i	n 1 g
CLOTRIMAZOLE (UNII: G07GZ97H		G07GZ97H65)				n 1 g
CLOTRIMAZOLE (UNII: G07GZ97F	i65) (CLOTRIMAZOLE - UNII: Ingredient Name	G07GZ97H65)			10 mg i	n 1 g
CLOTRIMAZOLE (UNII: G07GZ97H Inactive Ingredients WATER (UNII: 059QF0K00R)	i65) (CLOTRIMAZOLE - UNII: Ingredient Name	G07GZ97H65)			10 mg i	n 1 g
CLOTRIMAZOLE (UNII: G07GZ97H Inactive Ingredients WATER (UNII: 059QF0K00R) DIMETHICONE (UNII: 92RU3N3Y10	i65) (CLOTRIMAZOLE - UNII: Ingredient Name	G07GZ97H65)			10 mg i	n 1 g

POLYETHYLENE GI	LYCOL 400 (UNII: B697894SGQ)					
SOYBEAN OIL (UNI	: 241ATL177A)					
PANTHENOL (UNII:	WV9CM0067Z)					
CURDLAN (UNII: 693	30DL209R)					
SHEA BUTTER (UNI	I: K49155WL9Y)					
CAPRYLYL GLYCOI	. (UNII: 00YIU5438U)					
	M ANHYDROUS (UNII: 8NLQ36F6MM)					
.ALPHATOCOPHE	ROL ACETATE, DL- (UNII: WR1WPI7EW8)					
ALCOHOL (UNII: 3K	9958V90M)					
GLYCERIN (UNII: PD	C6A3C0OX)					
GLYCERYL CAPRYLATE (UNII: TM2TZ D4G4A)						
GLYCERYL MONOS	TEARATE (UNII: 2300U9XXE4)					
1,2-HEXANEDIOL (UNII: TR046Y3K1G)						
PEG-100 STEARATE (UNII: YD01N1999R)						
PROPYLENE GLYC	<b>DL</b> (UNII: 6DC9Q167V3)					
JOJOBA OIL (UNII: 724GKU717M)						
PEG-40 STEARATE	(UNII: ECU18C66Q7)					
CETOSTEARYL ALC	COHOL (UNII: 2DMT128M1S)					
POLYSORBATE 60	(UNII: CAL22UVI4M)					
Packaging						
# Item Code	Package Description	Marketing Start Date	Marketing End Date			
<b>1</b> 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 Dru	g M005	10/25/2021				

# Labeler - PureTek Corporation (785961046)

Revised: 10/2024

PureTek Corporation