

CLOTRIMAZOLE 1% TOPICAL ANTIFUNGAL CREAM- clotrimazole 1% antifungal cream cream
Mohnark Pharmaceuticals Inc.

DRUG FACTS

ACTIVE INGREDIENT

Clotrimazole 1%

PURPOSE

Antifungal

cures most athlete's foot, jock itch and ringworm

relieves itching, burning, cracking, scaling and discomfort which accompany these conditions.

WARNINGS

For external use only

Do not use on children under 2 years of age unless directed by a doctor

When using this product avoid contact with eyes

Stop use and ask a doctor if

- irritation occurs
- there is no improvement within 4 weeks (for athlete's foot or ringworm) or 2 weeks (for jock itch)

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

STOP USE AND ASK DOCTOR IF

irritation occurs

there is no improvement within 4 weeks (for athlete's foot or ringworm) or 2 weeks (for jock itch)

DIRECTIONS

- wash affected area and dry thoroughly
- apply a thin layer over affected area twice daily (morning and night)
- supervise children in the use of this product
- for athlete's foot, pay special attention to the spaces between the toes, wear well

fitting, ventilated shoes and change 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, ask a doctor
- this product is not effective on the scalp or nails

OTHER INFORMATION

- To open: unscrew cap, remove liner seal and replace cap
- Store at USP controlled room temperature 20-25°C (68-77°F)
- see carton or tube crimp for lot number and expiration date

INACTIVE INGREDIENTS

benzyl alcohol (1%), cetostearyl alcohol, cetyl esters wax, 2-octyldodecanol, polysorbate 60, purified water, sorbitan monostearate

DOSAGE AND ADMINISTRATION

10 milligrams/gram per application

INDICATIONS AND USAGE

Adults and children 2 years and older: apply externally to the affected area twice a day (morning and night).

Children under 2 years of age: consult a doctor

KEEP OUT OF REACH OF CHILDREN

If swallowed, get medical help or contact a Poison Control Center right away

PRINCIPAL DISPLAY PANEL



CLOTRIMAZOLE 1% TOPICAL ANTIFUNGAL CREAM

clotrimazole 1% antifungal cream cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73715-004
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CLOTRIMAZOLE (UNII: G07GZ97H65) (CLOTRIMAZOLE - UNII:G07GZ97H65)	CLOTRIMAZOLE	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)	1 g in 100 g
WATER (UNII: 059QF0KO0R)	69.5 g in 100 g
POLYSORBATE 60 (UNII: CAL22UVI4M)	1.5 g in 100 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73715-004-01	28 g in 1 TUBE; Type 0: Not a Combination Product	12/21/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M005	12/21/2020	

Labeler - Mohnark Pharmaceuticals Inc. (117013830)

Establishment

Name	Address	ID/FEI	Business Operations
Mohnark Pharmaceuticals Inc.		117013830	manufacture(73715-004)

Revised: 1/2024

Mohnark Pharmaceuticals Inc.