

CLOTRIMAZOLE- clotrimazole solution
GRAXCELL PHARMACEUTICAL, LLC.

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.

CLOTRIMAZOLE (TOPICAL SOLUTION) USP, 1%, 70795-8020

DRUG FACTS

ACTIVE INGREDIENT

CLOTRIMAZOLE USP, 1%

PURPOSE

ANTIFUNGAL

USES

Cures most

- Athlete's foot (tinea pedis)
- Jock Itch (tinea cruris)
- Ringworm (tinea corporis)

Effectively relieves

- itching
- cracking
- burning

Discomfort which can accompany these conditions

warnings

- For external use only

Ask a doctor before use

on children under 2 years of age

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 and 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.

Directions

This product is not effective on the scalp or nails. For best results, follow directions and continue treatment for length of time indicated. For athlete's foot and ringworm: use daily for 4 weeks. For jock itch: use daily for 2 weeks.

- clean the affected area and dry thoroughly
- apply a thin layer of the product over 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; change shoes and socks at least once daily.

other information

- Store at 15° to 30°C (59° to 86°F)

inactive ingredients

polyethylene glycol 400

questions?

please call 1-888-266-8818



CLOTRIMAZOLE			
clotrimazole solution			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70795-8020

Route of Administration	TOPICAL
--------------------------------	---------

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70795-8020-1	10 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/08/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	12/08/2017	

Labeler - GRAXCELL PHARMACEUTICAL, LLC. (056556923)

Establishment

Name	Address	ID/FEI	Business Operations
GRAXCELL PHARMACEUTICAL, LLC.		056556923	manufacture(70795-8020)

Revised: 12/2021

GRAXCELL PHARMACEUTICAL, LLC.