# CLOTRIMAZOLE- clotrimazole solution Marlex Pharmaceuticals Inc

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### Clotrimazole Solution

## **CLOTRIMAZOLE** -clotrimazolesolutionMarlexPharmaceuticals, Inc.

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.

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## **ClotrimazoleTopical Solution USP,1%**

## **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

## 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 ingredient**

polyethylene glycol 400

### PRINCIPAL DISPLAY PANEL - 10 mL Bottle Carton

NDC 10135-0671-81

Compare to the active ingredient of Lotrimin ®AF\*

## ClotrimazoleTopical Solution USP,1%

## **Antifungal**

- Relieves Itching & Burning
- Greaseless, Nonstaining

For External use only.

Not for Opthalmic use.

Keep this and all medications out of the reach of children.

## MarlexPharmaceuticals, Inc.

#### 10mL



## PRINCIPAL DISPLAY PANEL

NDC 10135-0671-91 Clotrimazole Topical Solution USP, 1 % 30 mL Rx Only



## Clotrimazole USP, 1%

(Topical Solution)

### Drug Facts (continued)

#### Stop use and ask 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, molean the affected area and dry thoroughly mapply 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:

### Drug Facts (continued)

pay special attention to spaces between the toes; wear well-fitting, ventilated shoes; change shoes and socks at least once daily.

### Other information

store between 15-30°C (59-86°F)

### Inactive ingredients polyethylene glycol

Keep this carton for important information.

Manufactured for and Distributed by: Marlex Pharmapeuticals, Inc. New Castle, DE 19720

VAII trademarks are property of their respective owners. This product is not at Baled with the makers/persers of Lotrimin\* AF.

REV. 01/20 IT

COATING FREE AREA

#### NDC 10135-0671-91

<sup>†</sup>Compare to the active ingredient of Lotrimin® AF

### MARLEX PHARMACKUTICALS, INC.

# Clotrimazole USP, 1%

- (Topical Solution)
- . Relieves Itching & Burning · Greaseless, Non-staining

## Antifungal

For External use only. Not for Ophthemic use,

Keep this and all medications out of the reach of children.

30 ml (1 fl oz)

TAMPER EVIDENT: This bottle has an imprinted seal around the neck. Do not use if seal is damaged or missing at the time of purchase.

## Drug Facts

## Active ingredient Purpose

Clotrimazole USP, 1% \_\_\_\_.

#### **Uses** Cures most

- Athlete's foot (tinea pedis),
- Jock Itch (tinea cruris),
- Ringworm (tines corports) 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



## **CLOTRIMAZOLE**

clotrimazole solution

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10135-671
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name	<b>Basis of Strength</b>	Strength		
CLOTRIMAZOLE (UNII: G07GZ97H65) (CLOTRIMAZOLE - UNII:G07GZ97H65)	CLOTRIMAZOLE	1 g in 1 mL		

Inactive Ingredients	
Ingredient Name	Strength
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:10135-671- 81	1 in 1 CARTON	12/01/2018			
1		10 mL in 1 BOTTLE; Type 0: Not a Combination Product				
2	NDC:10135-671- 91	1 in 1 CARTON	02/01/2020			
2		30 mL in 1 BOTTLE; Type 0: Not a Combination Product				

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M005	12/01/2018		

# **Labeler -** Marlex Pharmaceuticals Inc (782540215)

Revised: 11/2023 Marlex Pharmaceuticals Inc