

CLOTRIMAZOLE - clotrimazole solution
Akron Pharma 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.

Clotrimazole Topical 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

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 ingredient

polyethylene glycol 400

Questions?

Please Call **1-877-225-6999**

PRINCIPAL DISPLAY PANEL - 10 mL Bottle Carton

NDC 71399-0500-1

Compare to the active ingredient of Lotrimin® AF*

Clotrimazole Topical Solution USP, 1%

Antifungal

- *Relieves Itching & Burning*
- *Greaseless, Nonstaining*

For External use only.

Not for Ophthalmic use.

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

Akron Pharma

10ml

Drug Facts (continued)**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.

Drug Facts (continued)**Other Information**

- Store between 15°-30°C (59°-86°F)

Inactive Ingredients
polyethylene glycol 400

Manufactured for:
Akron Pharma, Inc., Fairfield, NJ 07004

Compare to the active ingredient of Lotrimin*

10ml

NDC: 71399-0500-1

Clotrimazole (Topical Solution) USP, 1% Anti fungal

- Relieves Itching & Burning
- Greaseless, Non-staining

For External use only,
Not for Ophthalmic use.

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

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 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.

Questions?
Please call 1-877-225-6999

* This product is not manufactured by Shering-Plough Healthcare Products Inc., owner of the registered trademark Lotrimin® AF

Akron Pharma

□□□

CLOTTRIMAZOLE

clotrimazole solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71399-0500
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:71399-0500-1	10 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/15/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part333C	05/15/2017	

Labeler - Akron Pharma Inc (067878881)

Registrant - Akron Pharma Inc (067878881)

Revised: 5/2017

Akron Pharma Inc