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

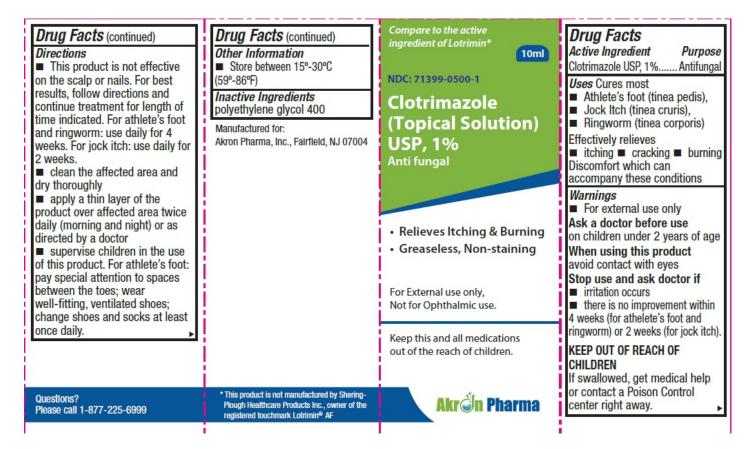
- Relieves Itching & Burning
- Greaseless, Nonstaining

For External use only. Not for Opthalmic use.

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

Akron Pharma

10_{ml}



NDC 71399-0500-3

Compare to the active ingredient of Lotrimin®AF*

Clotrimazole Topical Solution USP,1%

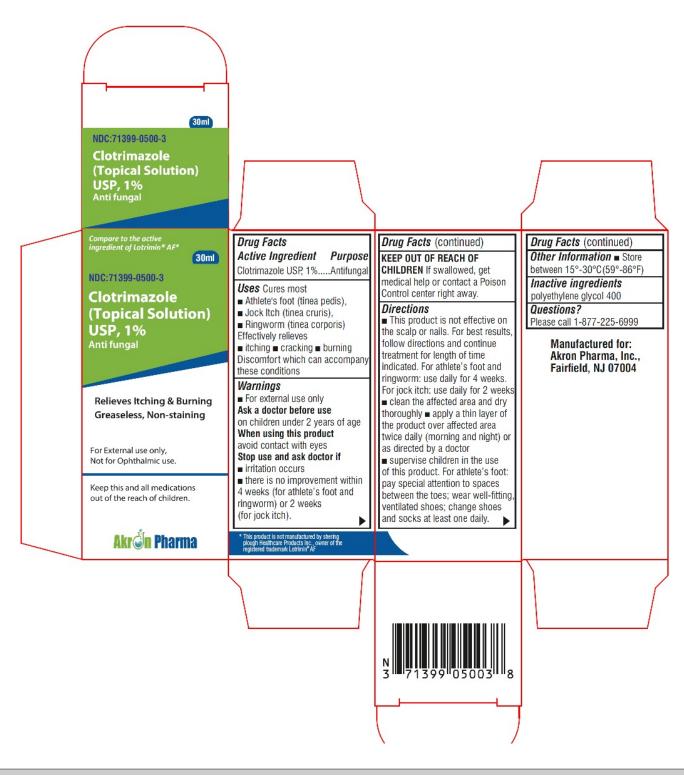
Antifungal

Relieves Itching & Burning Greaseless, Nonstaining For External use only. Not for Opthalmic use.

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

Akron Pharma

30_ml



CLOTRIMAZOLE

clotrimazole solution

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|----------------------------------|----------------|--------------------|---------|----------|--|
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| Product Information | | | | | |
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:713 | 99-0500 | |
| Route of Administration | TOPICAL | | | | |
| | | | | | |
| Active Increasiont/Active Meight | | | | | |
| Active Ingredient/Active Moiety | | | | | |
| Ingredient Name | | Basis of St | rength | Strength | |

| Clotrimazole (UNII: G07GZ97H65) (Clotrimazole - UNII:G07GZ97H65) | Clotrimazole | 1g in 1 mL |
|--|--------------|------------|
|--|--------------|------------|

| Inactive Ingredients | | | |
|--|----------|--|--|
| Ingredient Name | Strength | | |
| polyethylene glycol 400 (UNII: B697894SGQ) | | | |

| F | Packaging | | | | |
|---|----------------------|--|-------------------------|-----------------------|--|
| # | tem 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 | | |
| 2 | NDC:71399- 0500-3 | 30 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)

| Establishment | | | | | |
|-------------------------|---------|-----------|----------------------------|--|--|
| Name | Address | ID/FEI | Business Operations | | |
| SLV PHARMACEUTICALS LLC | | 081225162 | manufacture(71399-0500) | | |

Revised: 2/2023 Akron Pharma Inc