

CLOTRIMAZOLE- clotrimazole solution
ACINO PRODUCTS LIMITED LIABILITY COMPANY

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.

ACINO PRODUCTS - CLOTRIMAZOLE (TOPICAL SOLUTION) USP 1%

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
- 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.

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

call 1-877-227-2594

<p>Drug Facts (continued)</p> <p>Keep out of reach of children If swallowed, get medical help or contact a Poison Control Center right away.</p> <p>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.</p> <ul style="list-style-type: none"> ■ 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. <p>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.</p>	<p>Drug Facts (continued)</p> <p>Other information Store at 15° to 30°C (59° to 86°F)</p> <p>Inactive ingredient polyethylene glycol 400</p> <p>Questions? call 1-877-227-2594</p> <p><small>*This product is not manufactured by Shering Plough Healthcare Products Inc., owner of the registered trademark Lotrimin™ AF</small></p> <p>Manufactured by: Acino Products, LLC 9 B South Gold Drive Hamilton, NJ 08691. MADE IN USA</p> 	<p style="text-align: right;">NDC 68784-301-10</p>  <p style="text-align: center;">Compare to the active ingredient of Lotrimin AF*</p> <h2 style="text-align: center;">Clotrimazole (Topical Solution) USP, 1%</h2> <p style="text-align: center; background-color: yellow;">Antifungal</p> <p style="text-align: center;">Relieves Itching & Burning</p> <ul style="list-style-type: none"> • Greaseless • Non-staining <p style="text-align: center;">External use only. Not for Ophthalmic use.</p> <p style="text-align: center;">Keep this and all medications out of the reach of children.</p> <p style="text-align: center; font-size: 1.2em;">10mL Bottle</p>	<p>Drug Facts</p> <p>Active ingredient Purpose Clotrimazole USP, 1%... Antifungal</p> <p>Uses Cures most</p> <ul style="list-style-type: none"> ■ Athlete's foot (tinea pedis) ■ Jock Itch (tinea cruris) ■ Ringworm (tinea corporis) <p>Effectively relieves ■ Itching ■ Cracking ■ Burning Discomfort which can accompany these conditions</p> <p>Warnings</p> <ul style="list-style-type: none"> ■ For external use only <p>Ask a doctor before use on children under 2 years of age</p> <p>When using this product avoid contact with eyes</p> <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> ■ irritation occurs ■ there is no improvement within 4 weeks (for athlete's foot and ringworm) or 2 weeks (for jock itch)
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CLOTRIMAZOLE

clotrimazole solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68784-301
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 mL

Inactive Ingredients

Ingredient Name	Strength
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68784-301-10	1 in 1 BOX	07/29/2019	
1	NDC:68784-301-01	10 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 final	part333C	07/29/2019	

Labeler - ACINO PRODUCTS LIMITED LIABILITY COMPANY (019385518)

Establishment

Name	Address	ID/FEI	Business Operations
ACINO PRODUCTS LIMITED LIABILITY COMPANY		019385518	manufacture(68784-301)

Revised: 5/2021

ACINO PRODUCTS LIMITED LIABILITY COMPANY