

FASTRIN ANTI - FUNGAL SKIN CARE- clotrimazole ointment

Aidance Skincare & Topical Solutions, 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.

Drug Facts

Active Ingredient

Clotrimazole 1%

Purpose

Antifungal

Uses

Cures most fungal skin infections, including ringworm and tinea. For effective relief of itching, scaling, cracking, burning, discoloration, soreness, irritation, discomfort, redness and chafing associated with fungal skin infections.

Warnings

For external use only. Do not use on children under two years of age unless directed by a physician. **When using this product** avoid contact with the eyes. **Stop use and ask a doctor if** irritation occurs or if there is no improvement within 4 weeks.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center immediately.

Directions

Clean and dry affected skin. Apply a thin layer of ointment over the affected area twice daily (morning and night) or as directed by a doctor.

Inactive Ingredients

Beeswax, Cottonseed Oil, Jojoba Seed Oil, Magnesium Oxide, Manuka Honey, Peppermint Oil, Silver Oxide, Tea Tree Oil, Zinc Oxide

PRINCIPAL DISPLAY PANEL - 50g Tube

Fastrin

Anti - Fungal

Skin Care Ointment

Net WT 50g (1.76 oz.)

DRUG FACTS**Active Ingredient & Purpose:** Clotrimazole 1% (Antifungal)**Uses:** Cures most fungal skin infections, including ringworm and tinea. For effective relief of itching, scaling, cracking, burning, discoloration, soreness, irritation, discomfort, redness and chafing associated with fungal skin infections.**Warnings:** For external use only. Do not use on children under two years of age unless directed by a physician. When using this product avoid contact with the eyes. Stop use and ask a doctor if irritation occurs or if there is no improvement within 4 weeks. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.**Directions:** Clean and dry affected skin. Apply a thin layer of ointment over the affected area twice daily (morning and night) or as directed by a doctor.**Inactive Ingredients:** Beeswax, Cottonseed Oil, Jojoba Seed Oil, Magnesium Oxide, Manuka Honey, Peppermint Oil, Silver Oxide, Tea Tree Oil, Zinc Oxide**Fastrin[™]** 
Anti-Fungal Skin Care Ointment**Eliminates fungus 6X faster**
Great for treatment and prevention
Provides fast, soothing relief **Aspiera Medical[™]**
Faster Healing Lowers the Cost of Care[™]Learn more and purchase at
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FASTRIN ANTI - FUNGAL SKIN CARE

clotrimazole ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:24909-601
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CLOTRIMAZOLE (UNII: G07GZ97H65) (CLOTRIMAZOLE - UNII:G07GZ97H65)	CLOTRIMAZOLE	1.0 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
COTTONSEED OIL (UNII: H3E878020N)	
HONEY (UNII: Y9H1V576FH)	
JOJOBA OIL (UNII: 724GKU717M)	
MAGNESIUM OXIDE (UNII: 3A3U0G171G)	
PEPPERMINT OIL (UNII: AV092KU4JH)	

SILVER OXIDE (UNII: 897WUN6G6T)

TEA TREE OIL (UNII: VIF565UC2G)

WHITE WAX (UNII: 7G1J5DA97F)

ZINC OXIDE (UNII: SOI2LOH54Z)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24909-601-10	10 g in 1 JAR; Type 0: Not a Combination Product	06/01/2017	
2	NDC:24909-601-50	50 g in 1 TUBE; Type 0: Not a Combination Product	06/01/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	06/01/2017	

Labeler - Aidance Skincare & Topical Solutions, LLC (018950611)

Establishment

Name	Address	ID/FEI	Business Operations
Aidance Skincare & Topical Solutions, LLC		018950611	manufacture(24909-601) , label(24909-601)

Revised: 6/2017

Aidance Skincare & Topical Solutions, LLC