

MAJOR CLOTRIMAZOLE- clotrimazole cream

A-S Medication Solutions

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 USP 1% w/w

Purpose

Antifungal Cream

Uses

Cures athlete's foot (tinea pedis), jock itch (tinea cruris), ringworm (tinea corporis). Relieves the itching, irritation, redness, scaling and discomfort which can accompany these conditions.

Warnings

- **Do not use on children under 2 years of age unless directed by a doctor.**
- **For external use only.**
- **Avoid contact with eyes.**
- If irritation occurs or if there is no improvement within 4 weeks (for athlete's foot or ringworm) or within 2 weeks (for jock itch), discontinue use and consult a doctor.
- **Keep this and all drugs out of the reach of children.**

In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.

Directions

- Clean the affected area and dry thoroughly.
- Apply a thin layer of this 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 the spaces between the toes; wear well-fitting ventilated shoes, and change shoes and socks at least once daily.
- For athlete's foot and ringworm, use daily for 4 weeks. For jock itch, use daily for 2 weeks.
- If conditions persists longer, consult a doctor.

- This product is not effective on the scalp or nails.

Other information

- Store at controlled room temperature 15°-30°C (59°-86°F).
- Close cap tightly after use.

Inactive ingredients

aloe vera, benzyl alcohol, cetearyl alcohol, 2-octyldodecanol, polysorbate 60, sorbitan monostearate, spermwax, vitamin E, water

Questions?

Adverse Drug Event call (800)616-2471
 Dist. By MAJOR PHARMACEUTICALS
 31778 Enterprise Drive, Livonia, MI 48150 USA
 Re-Order No. 100431

HOW SUPPLIED

Product: 50090-2570
 NDC: 50090-2570-0 28.35 g in a TUBE / 1 in a CARTON

CLOTRIMAZOLE



MAJOR CLOTRIMAZOLE			
clotrimazole cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50090-2570(NDC:0904-7822)

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CLOTRIMAZOLE (UNII: G07GZ97H65) (CLOTRIMAZOLE - UNII:G07GZ97H65)	CLOTRIMAZOLE	10 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
CETYL PALMITATE (UNII: 5ZA2S6B08X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50090-2570-0	1 in 1 CARTON	10/28/2016	
1		28.35 g in 1 TUBE; 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	10/04/2004	

Labeler - A-S Medication Solutions (830016429)

Establishment

Name	Address	ID/FEI	Business Operations
A-S Medication Solutions		830016429	RELABEL(50090-2570)