

JOCK ITCH CREAM WITH CLOTRIMAZOLE- clotrimazole cream
Sabel Med 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.

Jock Itch Cream with 1% Clotrimazole

Warnings

For external use only

Do not use on children under 2 years of age, unless directed by a doctor

Stop use and ask a doctor if

- irritation occurs
- there is no improvement within 4 weeks
- **Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

Distributed by: Sabel Med LLC

Directions

- wash affected area and dry thoroughly
- apply a thin layer over affected area twice daily (morning and night)
- supervise children in the use of this product
- use daily for 4 weeks ■ if condition persists longer, ask a doctor
- this product is not effective on the scalp or nails

Inactive ingredients cetomacrogol 1000, cetostearyl alcohol, liquid paraffin, methylparaben, propylene glycol, propylparaben, purified water, white soft paraffin

Active ingredients

Clotrimazole 1%

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Purpose

..... Antifungal

Uses ■ cures most jock itch ■ relieves itching, burning, scaling, discomfort and chafing associated with jock itch ■ for treating ringworm

2 mm BG Area can be extend but after formation of the tube will come on back panel



Net wt 1oz. (28 g)

Jock Itch Cream

Clotrimazole Cream USP 1%

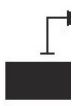
NDC 70356-051-01

Relieves Itching & Burning

Antifungal Jock itch cream used for relief from itching and burning caused by jock itch

Drug Facts Active ingredients Clotrimazole 1% Antifungal Purpose Antifungal		Drug Facts (continued) Directions ■ wash affected area and dry thoroughly ■ apply a thin layer over affected area twice daily (morning and night) ■ supervise children in the use of this product ■ use daily for 4 weeks ■ if condition persists longer, ask a doctor ■ this product is not effective on the scalp or nails	
Uses ■ cures most jock itch ■ relieves itching, burning, scaling, discomfort and chafing associated with jock itch ■ for treating ringworm		Other information ■ store at 15° and 30°C (36° and 86°F) ■ avoid excess heat and humidity	
Warnings For external use only Do not use on children under 2 years of age, unless directed by a doctor Stop use and ask a doctor if ■ irritation occurs ■ there is no improvement within 4 weeks ■ Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.		Inactive ingredients cetomacrogol 1000, cetostearyl alcohol, liquid paraffin, methylparaben, propylene glycol, propylparaben, purified water, white soft paraffin	
Distributed by: Sabel Med LLC Oldsmar, FL 34677 Aftate™ RetroBrands U.S.A. LLC 2016		Retain carton for important product information Made in India MH/DRUGS/KD-180	

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JOCK ITCH CREAM WITH CLOTRIMAZOLE

clotrimazole cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70356-051
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 g

Inactive Ingredients

Ingredient Name	Strength
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0K00R)	
PARAFFIN (UNII: I9O0E3H2ZE)	
CETETH-20 (UNII: I835H2IHHX)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
MINERAL OIL (UNII: T5L8T28FGP)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70356-051-01	28 g in 1 TUBE; Type 0: Not a Combination Product	05/01/2016	
2	NDC:70356-051-05	14 g in 1 TUBE; Type 0: Not a Combination Product	05/01/2016	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	05/01/2016	

Labeler - Sabel Med LLC (091476000)

Revised: 4/2016

Sabel Med LLC