SILKA RINGWORM- clotrimazole cream Genomma Lab USA, 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.

Silka[®]

Ringworm

Drug Facts

Active ingredient

Clotrimazole 1%

Purpose

Antifungal

Uses

- cures most ringworm
- relieves itching, redness, irritation and discomfort which accompany this condition

Warnings

For external use only

When using this product avoid contact with the eyes

Stop use and ask a doctor if

- irritation occurs
- there is no improvement within 4 weeks

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

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

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

Other information

- To open: unscrew cap, use the pointed end of cap to puncture seal.
- store between 20° 25°C (68° 77°F)
- see carton or tube crimp for lot number and expiration date

Inactive ingredients

benzyl alcohol (1%), cetostearyl alcohol, cetyl esters wax, 2-octyldodecanol, polysorbate 60, purified water, sorbitan monostearate

Questions?

Call 1877 99 GENOM (43666)

Distributed by: Genomma Lab USA Inc., Houston, TX, 77027

PRINCIPAL DISPLAY PANEL - 14.2 g Tube Carton

SILKA[®]
Clotrimazole Cream USP, 1%
ANTIFUNGAL CREAM
CURES MOST RINGWORM
NET WT 0.5 oz (14.2 g)



SILKA

Clotrimazole Cream USP, 1% **ANTIFUNGAL CREAM**

CURES MOST RINGWORM

CURES MOST RINGWORM

- Relieves Itching, Redness & Irritation
- For Adults and Children 2 Years & Older



NET WT 0.5 oz (14.2 g)

Made in Canada Distributed by: Genomma Lab USA Inc., Houston, TX, 77027

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CURES MOST RINGWORM

Clotrimazole Cream USP, 1%

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SILKA RINGWORM

clotrimazole cream

Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50066-111		
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		
benzyl alcohol (UNII: LKG8494WBH)			
cetostearyl alcohol (UNII: 2DMT128M1S)			
cetyl esters wax (UNII: D072FFP9GU)			
octyldodecanol (UNII: 461N1O614Y)			
polysorbate 60 (UNII: CAL22UVI4M)			
sorbitan monostearate (UNII: NVZ4I0H58X)			
water (UNII: 059QF0KO0R)			

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1 NDC:50066-111-05	1 in 1 CARTON	12/21/2018		
1	14.2 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	06/01/1995			

Labeler - Genomma Lab USA, Inc. (832323534)

Revised: 1/2019 Genomma Lab USA, Inc.