

SILKA JOCK ITCH- terbinafine hydrochloride cream
Genomma Lab USA, Inc.

Silka®

Jock Itch

Drug Facts

Active ingredient

Terbinafine hydrochloride 1%

Purpose

Antifungal

Uses

- cures most jock itch (tinea cruris)
- relieves itching, burning, cracking and scaling which accompany this condition

Warnings

For external use only

Do not use

- on nails or scalp
- in or near the mouth or eyes
- for vaginal yeast infections

When using this product do not get into eyes. If eye contact occurs, rinse thoroughly with water.

Stop use and ask a doctor if too much irritation occurs or gets worse

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

Directions

- adults and children 12 years and over:
 - use the tip of the cap to break the seal and open the tube
 - wash the affected skin with soap and water and dry completely before applying
 - apply once a day (morning **or** night) for **1 week** or as directed by a doctor
 - wash hands after each use
- children under 12 years: ask a doctor

Other information

- do not use if seal on tube is broken or is not visible
- store at controlled room temperature 20° to 25°C (68° to 77°F)
- see carton or tube crimp for lot number and expiration date

Inactive ingredients

benzyl alcohol, cetyl alcohol, cetyl palmitate, isopropyl myristate, polysorbate 60, purified water, sodium hydroxide, sorbitan monostearate, stearyl alcohol

Questions?

call **1 877 99 GENOM (43666)**

Distributed by:

Genomma Lab USA Inc., Houston, TX, 77027

PRINCIPAL DISPLAY PANEL - 15 g Tube Carton

SILKA®

Terbinafine Hydrochloride Cream 1%

ANTIFUNGAL CREAM

FULL PRESCRIPTION

STRENGTH

JOCK ITCH

CURES MOST JOCK ITCH

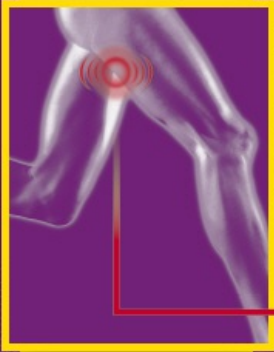
NET WT 0.5 oz (15 g)

SILKA[®]

Terbinafine Hydrochloride Cream 1%
ANTIFUNGAL CREAM

JOCK ITCH

CURES MOST JOCK ITCH



- » Relieves Itching & Burning
- » Full Prescription Strength

CURES MOST JOCK ITCH

T174
B75.2
ENG19.53



FULL PRESCRIPTION STRENGTH

SILKA[®]

Terbinafine Hydrochloride Cream 1%
ANTIFUNGAL CREAM

JOCK ITCH

CURES MOST JOCK ITCH NET WT 0.5 oz (15 g)

SILKA[®]
Terbinafine Hydrochloride Cream 1%
ANTIFUNGAL CREAM

NO COPY ON THIS
FLAP FOR LOT #
AND EXPIRY
DATE PRINT

LPK-8911-0
1218-0
65



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

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NO VARNISH
ON THIS FLAP

NO VARNISH
ON THIS FLAP

Drug Facts Terbinafine hydrochloride 1%.....Antifungal	Uses • cures most jock itch (thinea cruris) • relieves itching, burning, cracking and scaling which accompany this condition	Warnings For external use only Do not use • on nails or scalp • in or near the mouth or eyes • for vaginal yeast infections When using this product do not get into eyes. If eye contact occurs, rinse thoroughly with water. Stop use and ask a doctor if too much irritation occurs or gets worse Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	Directions • adults and children 12 years and over: use the tip of the cap to break the seal and open the tube
Drug Facts (continued) • wash the affected skin with soap and water and dry completely before applying • apply once a day (morning or night) for 1 week or as directed by a doctor • wash hands after each use • children under 12 years: ask a doctor	Other information • do not use if seal on tube is broken or its not visible • store at controlled room temperature 20° to 25°C (68° to 77°F) • see carton or tube crimp for lot number and expiration date	Inactive ingredients benzyl alcohol, cetyl alcohol, cetyl palmitate, isopropyl myristate, poly sorbate 60, purified water, sodium hydroxide, sorbitan monostearate, stearyl alcohol	Questions? call 1 877 99 GENOM (43666)

JOCK ITCH

Terbinafine Hydrochloride Cream 1%
ANTIFUNGAL CREAM



SILKA JOCK ITCH

terbinafine hydrochloride cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50066-208
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Terbinafine Hydrochloride (UNII: 012C11ZU6G) (Terbinafine - UNII:G7RIW8S0XP)	Terbinafine Hydrochloride	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
benzyl alcohol (UNII: LKG8494WBH)	
cetyl alcohol (UNII: 936JST6JCN)	
cetyl palmitate (UNII: 5ZA2S6B08X)	
isopropyl myristate (UNII: 0RE8K4LNJS)	
polysorbate 60 (UNII: CAL22UVI4M)	
water (UNII: 059QF0KO0R)	
sodium hydroxide (UNII: 55X04QC32I)	
sorbitan monostearate (UNII: NVZ4I0H58X)	
stearyl alcohol (UNII: 2KR89I4HIY)	

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50066-208-05	1 in 1 CARTON	12/20/2018	
1		15 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
ANDA	ANDA077511	07/02/2007	

Labeler - Genomma Lab USA, Inc. (832323534)

Revised: 1/2019

Genomma Lab USA, Inc.