

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

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**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<sup>®</sup>

Terbinafine Hydrochloride Cream 1%

ANTIFUNGAL CREAM

FULL PRESCRIPTION

STRENGTH

JOCK ITCH

CURES MOST JOCK ITCH

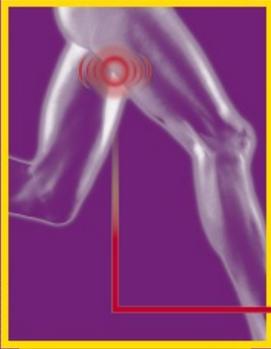
NET WT 0.5 oz (15 g)

# SILKA<sup>®</sup>

Terbinafine Hydrochloride Cream 1%  
ANTIFUNGAL CREAM

## JOCK ITCH

CURES MOST JOCK ITCH



CURES MOST JOCK ITCH

- » Relieves Itching & Burning
- » Full Prescription Strength

T174  
B75.2  
ENG19.53



FULL PRESCRIPTION STRENGTH

# SILKA<sup>®</sup>

Terbinafine Hydrochloride Cream 1%  
ANTIFUNGAL CREAM

## JOCK ITCH

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

SILKA<sup>®</sup>  
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

2000007600

NO VARNISH ON THIS FLAP

NO VARNISH ON THIS FLAP

<b>Drug Facts</b> Terbinafine hydrochloride 1%.....Antifungal	<b>Uses</b> • cures most jock itch (thinea cruris) • relieves itching, burning, cracking and scaling which accompany this condition	<b>Warnings</b> 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.	<b>Directions</b> • adults and children 12 years and over: use the tip of the cap to break the seal and open the tube
<b>Drug Facts (continued)</b> • 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	<b>Other information</b> • 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	<b>Inactive ingredients</b> benzyl alcohol, cetyl alcohol, cetyl palmitate, isopropyl myristate, polysorbate 60, purified water, sodium hydroxide, sorbitan monostearate, stearyl alcohol	<b>Questions?</b> call 1 877 99 GENOM (43666)

## JOCK ITCH

Terbinafine Hydrochloride Cream 1%  
ANTIFUNGAL CREAM



## SILKA JOCK ITCH

terbinafine hydrochloride cream

### Product Information

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

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>TERBINAFINE HYDROCHLORIDE</b> (UNII: 012C11ZU6G) (TERBINAFINE - UNII:G7RIW8S0XP)	TERBINAFINE HYDROCHLORIDE	1 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
<b>BENZYL ALCOHOL</b> (UNII: LKG8494WBH)	
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
<b>CETYL PALMITATE</b> (UNII: 5ZA2S6B08X)	
<b>ISOPROPYL MYRISTATE</b> (UNII: 0RE8K4LNJS)	
<b>POLYSORBATE 60</b> (UNII: CAL22UVI4M)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>SORBITAN MONOSTEARATE</b> (UNII: NVZ4I0H58X)	
<b>STEARYL ALCOHOL</b> (UNII: 2KR89I4H1Y)	

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### 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			
<b>Marketing Information</b>			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077511	07/02/2007	

**Labeler** - Genomma Lab USA, Inc. (832323534)

### Establishment

Name	Address	ID/FEI	Business Operations
Sun Pharma Canada Inc.		243339023	manufacture(50066-208)

Revised: 7/2025

Genomma Lab USA, Inc.