# SILKA ANTIFUNGAL- terbinafine hydrochloride cream Genomma Lab USA, Inc.

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Silka <sup>®</sup>Antifungal

**Drug Facts** 

# **Active ingredient**

Terbinafine hydrochloride 1%

# **Purpose**

**Antifungal** 

#### Uses

- cures most athlete's foot (tinea pedis)
- cures most jock itch (tinea cruris) and ringworm (tinea corporis)
- relieves itching, burning, cracking and scaling which accompany these conditions

#### **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.
- **for athlete's foot**wear well-fitting, ventilated shoes. Change shoes and socks at least once daily.
- between the toes only:apply twice a day (morning and night) for 1 weekor as directed by a doctor.
- on the bottom or sides of the foot:apply twice a day (morning and night) for 2

weeksor as directed by a doctor.

- for jock itch and ringworm:apply once a day (morning ornight) for 1 weekor as directed by a doctor.
- wash hands after each use.
- children under 12 years: ask a doctor.

#### Other information

- TAMPER EVIDENT: DO NOT USE IF THE SEAL ON THE TUBE IS PUNCTURED OR 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?

**1 877 994 3666**Monday to Friday, 8 am to 6 pm Central time.

Distributed by:

Genomma Lab USA Inc., Houston, TX, 77027

# PRINCIPAL DISPLAY PANEL - 30 g Tube Carton

Terbinafine Hydrochloride Cream 1% - Antifungal

SILKA ®

ANTIFUNGAL CREAM FOR ATHLETE'S FOOT

Full prescription strength

NET WT.

1 oz (30 g)





# **HELPS RELIEVE: / AYUDA A ALIVIAR:**

- CRACKING
- SCALING
- COMEZÓN
- ARDOR
- AGRIETAMIENTO
- DESCAMACIÓN

CREMA ANTIHONGOS PARA EL PIE DE ATLETA

Questions? 1-877-994-3666 Monday to Friday, 8 am to 6 pm Central time.

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Terbinafine Hydrochloride Cream 1% - Antifungal / Crema de Clorhidrato de Terbinafina al 1% - Antihongos

#### FULL PRESCRIPTION STRENGTH

NET WT. 1 oz (30 g)



Made in Canada / Hecho en Canadá Distributed by / Distribuido por: Genomma Lab USA Inc., Houston, TX, 77098





2000013704

. Preguntas? 1-871-994- 3666 Lunes a viemes de 8 a. m. a 6 p. m. hora del centro.

ingredientes inactivos alconol benatico, alcohol cetilico, palmitato cetilico, miristato de espoppilo, polisorbato BO, agua purificada, hidróxido de sodio, sorbitano monosestearato, alcohol

Información adicional « Evidencia de Mauipulación: No utilizara si el sello del tudo esta rodo o no es visible. » consens el dempetadas adiviente controladada 20.25°C (88-77°F). « se a le conses o el tudo para a la direma de labera la peta a levandamiento.

plique una vez al dis (mañana **o** noche) durante **1 senrana** según indisación médica: sa manos después de cada uso. • niños menores de 12 años: consultar con un médico Institucciones e adultos y ninco mayores de 17 años de edad e use la brinta de la tapa bara romber el seljo y agua y adua y seque

Mantenga fuera del alcance de los minos. En caso de ingestión, busque asistencia médica o llame a un Centro de Control de Envenenamiento de inmediato.

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atastreete producto evite el contacto con los ojos. Si se produce contacto, No lo use e en las uñas ni en el cuero cabelludo e en ni cerca de la boca o los ojos e para micosis vaginal

quicemente para uso externo

**визининам** 

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otisògorq Principio activo Información sobre el medicamento

Antifungal

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Marnings relieves itching, burning, cracking and scaling which accompany these conditions cures most jock itch (tines cruris) and ringworm (tines corporis)

Uses - cures most athlete's foot (tinea pedis)

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Drug Facts

thoroughly with water.

For external use only

for vaginal yeast infections

petween the toes entre los dedos



# terbinafine hydrochloride cream

### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:50066-080

Route of Administration TOPICAL

# Active Ingredient/Active Moiety Ingredient Name Basis of Strength TERBINAFINE HYDROCHLORIDE (UNII: 012C11ZU6G) (TERBINAFINE - UNII:G7RIW8S0XP) TERBINAFINE 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: NVZ 410H58X)		
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)		

Product Characteristics			
Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50066-080- 02	1 in 1 CARTON	07/02/2007	
1		30 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:50066-080- 03	1 in 1 CARTON	05/21/2018	
2		30 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:50066-080- 05	1 in 1 CARTON	12/20/2018	
3		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)

Registrant - Taro Pharmaceuticals U.S. A., Inc. (145186370)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
Taro Pharmaceuticals Inc.		206263295	manufacture(50066-080)

Revised: 4/2024 Genomma Lab USA, Inc.