

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

Silka[®] 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 week** or as directed by a doctor.
- **on the bottom or sides of the foot:** apply twice a day (morning and night) for **2**

weeks or as directed by a doctor.

- **for jock itch and ringworm:** 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

- **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)



Clinicamente probado para aliviar la mayoría de casos de pie de atleta*

ANTIFUNGAL CREAM FOR ATHLETE'S FOOT / CREMA ANTIHONGOS PARA EL PIE DE ATLETA



HELPS RELIEVE: / AYUDA A ALIVIAR:

- ITCHING
- BURNING
- CRACKING
- SCALING

- COMEZÓN
- ARDOR
- AGRIETAMIENTO
- DESCAMACIÓN

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

FULL PRESCRIPTION STRENGTH

TAN POTENTE COMO EL TRATAMIENTO DE PRESCRIPCIÓN MÉDICA



ANTIFUNGAL CREAM FOR ATHLETE'S FOOT / CREMA ANTIHONGOS PARA EL PIE DE ATLETA

NET WT. 1 oz (30 g)

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



2000013704

T175

5248623
0224
45

NO VARNISH / NO AQ
NO COPY / NO COLOR
THIS FLAP FOR LOT #

NO VARNISH
ON THIS FLAP

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 week or as directed by a doctor. • on the bottom or sides of the foot: apply twice a day (morning and night) for 2 weeks or as directed by a doctor. • for jock itch and ringworm: 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 • 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, poly sorbate 60, purified water, sodium hydroxide, sorbitan monoesterate, stearyl alcohol.
Precautions • adults y niños mayores de 12 años de edad • use la punta de la tapa para romper el sello y abrir el tubo • lave el área de piel afectada con jabón y agua y seque completamente antes de la aplicación. • para el pie de atleta: use zapatos con buen cable y ventilados. Cambie los zapatos y las medias al menos una vez al día. • solamente entre los dedos del pie: aplique dos veces al día (mañana y noche) durante 1 semana o según indicación médica. • en la planta y en los costados del pie: aplique dos veces al día (mañana y noche) durante 2 semanas o según indicación médica. • en el caso de la ingesta accidental: llave después de cada uso • niños menores de 12 años: consultar con un médico.	Information to read • TAMPER EVIDENT: DO NOT USE IF THE SEAL ON THE TUBE IS PUNCTURED OR NOT VISIBLE • conserve a temperatura ambiente controlada de 20-25°C (68-77°F) • vea el empaque o el tubo para el número de lote o la fecha de vencimiento Ingredients alcohol benílico, alcohol cetílico, palmitato cetílico, miristato de isopropilo, polisorbato 60, agua purificada, hidróxido de sodio, sorbitano monoesterato, alcohol esteárico.
Advertencias Únase para uso externo No lo use • en las uñas ni en el cuero cabelludo • en ni cerca de la boca o los ojos • para micosis vaginal Al usar este producto evite el contacto con los ojos. Si se produce contacto, enjuáguelos de inmediato con abundante agua. Interumpa el uso y consulte con un médico en caso de excesiva irritación o si empeora. Mantenga fuera del alcance de los niños. En caso de ingestión, busque asistencia médica o llame a un Centro de Envenenamiento de inmediato.	Questions? 1-877-994-3666 Monday to Friday, 8 am to 6 pm Central time.
Propósito Antifúngico	Preguntas? 1-877-994-3666 Lunes a viernes de 8 a. m. a 6 p. m. hora del centro.
Información sobre el medicamento Principio activo Clorhidrato de terbinafina al 1%	
Usos • cura la mayoría de los casos de pie de atleta (tinea pedis) • cura la mayoría de los casos de tinea inguinal (tinea cruris) y tinea corporal (tinea corporis) • alivia el prurito, el ardor, el agrietamiento y la descamación que acompañan a estas afecciones.	

*between 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	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: NVZ4I0H58X)	
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)

Establishment

Name	Address	ID/FEI	Business Operations
Sun Pharma Canada Inc.		243339023	manufacture(50066-080)

Revised: 7/2025

Genomma Lab USA, Inc.