

SILKA GEL- terbinafine hydrochloride gel
All Natural Dynamics

Silka®

Gel

Drug Facts

Active ingredient

Terbinafine hydrochloride 1%

Purpose

Antifungal

Uses

- cures most athletes foot (tinea pedis)
- cures most jock itch (tinea cruris) and ring worm (tinea corporis)
- 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
 - **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 bottom or sides of feet:** apply twice a day (morning and night) for **2 weeks** or as directed by a doctor.
 - **for jock itch and ringworm:** apply twice a day (morning and 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:
PCGI Wholesale Chula Vista, CA, 91911

PRINCIPAL DISPLAY PANEL - 30g Tube Carton

SILKA®

Terbinafine Hydrochloride Cream 1%
Crema de clorhidrato de terbinafina al 1%

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Purpose
Antifungal

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• cures most jock itch (tinea cruris) and ringworm (tinea corporis)
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Warnings

For external use only
Do not use • on nails or scalp • in or near the mouth or the eyes
• for vaginal yeast infections
When using this product do not get into the eyes. If eye contact occurs, rinse thoroughly with water.
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Directions • adults and children 12 years and older • 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.

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Questions? 1 877 99 GENOM (43996) Monday to Friday, 8 am to 6 pm Central time.

Información sobre el medicamento

Principio activo
Clorhidrato de terbinafina 1%
Propósito
Antifúngico

Usos • cura la mayoría de los casos de pie de atleta (tinea pedis) • cura la mayoría de los casos de tija inguinal (tinea cruris) y tija corporal (tinea corporis) • alivia el prurito, el ardor, el agrietamiento y la descamación que acompañan a estas afecciones

Advertencias

Únicamente 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.
Interrumpa el uso y consulte con un médico en caso de • erucasia, irritación o si empeora.
Mantenga fuera del alcance de los niños. En caso de ingestión, busque asistencia médica o llame a un centro de control de envenenamiento de inmediato.

Instrucciones • adultos 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 calor 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 tija inguinal o tija corporal aplique una vez al día (mañana o noche) durante 1 semana según indicación médica. Evítese las manos después de cada uso. • niños menores de 12 años: consultar con un médico.

Información adicional • no lo use si el sello del tubo está roto o no es visible
• conserve a temperatura ambiente controlada de 20-25 °C (68-77 °F)
• vea el envase o el tubo para el número de lote o la fecha de vencimiento

Ingredientes inactivos alcohol benzílico, alcohol cetílico, palmitato cetílico, metilato de isopropilo, polisorbato 60, agua purificada, hidróxido de sodio, sorbitano monostearato, alcohol esteárico

Preguntas? 1 877 99 GENOM (43996) Lunes a viernes de 8 a. m. a 6 p. m. hora del centro.

SILKA GEL

terbinafine hydrochloride gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51769-121
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)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51769-121-30	30 g in 1 TUBE; Type 0: Not a Combination Product	01/18/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077511	01/18/2021	

Labeler - All Natural Dynamics (962732892)

Registrant - All Natural Dynamics (962732892)

Establishment

Name	Address	ID/FEI	Business Operations
Gelpharma S.A. de C.V.		812773665	manufacture(51769-121)

Revised: 1/2021

All Natural Dynamics