

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)



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)

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

Establishment

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

Revised: 4/2024

Genomma Lab USA, Inc.