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 ringworm (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

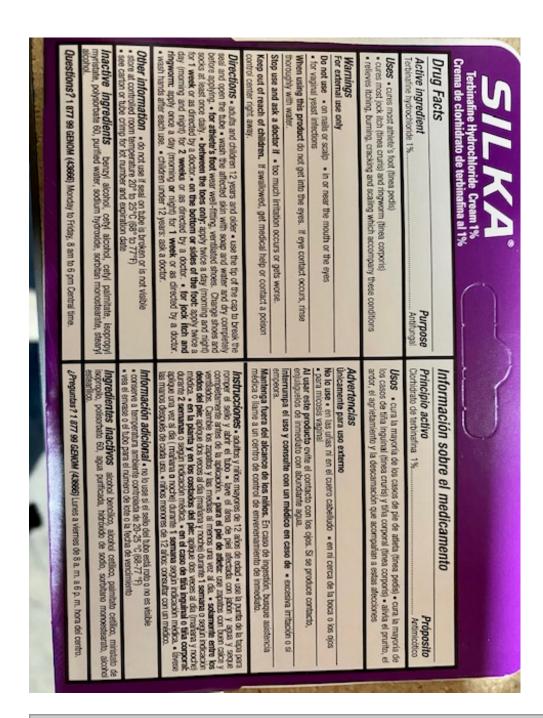
benzyl alcohol, cetyl alcohol, cetyl palmitate, isopropyl myristate, polysorbate 60, purified water, sodium hydroxide, sorbitan monostearate, stearyl alcohol

Questions?

call 1877 99 GENOM (43666)

Distributed by: PCGI Wholesale Chula Vista, CA, 91911

PRINCIPAL DISPLAY PANEL - 30g Tube Carton



SILKA GEL

terbinafine hydrochloride gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51769-121
Route of Administration	TOPICAL		

Ingredient Name	Basis of Strength	Strength
		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: 0 RE8 K4LNJS)		
POLYSORBATE 60 (UNII: CAL22UVI4M)		
WATER (UNII: 059QF0KO0R)		
SODIUM HYDROXIDE (UNII: 55X04QC32I)		
SORBITAN MONOSTEARATE (UNII: NVZ4I0 H58 X)		
STEARYL ALCOHOL (UNII: 2KR8914H1Y)		

l	Packaging			
l	# Item Code Package Description		Marketing Start Date	Marketing End Date
l	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