SYLVIRENE TATTOO NUMBING- lidocaine 4% tattoo numbing cream Jiangxi Hemei Pharmaceutical Co., Ltd

84010-080 Update

Active Ingredient

Lidocaine 4%

Purpose

Local Anesthetic

Use

For temporary relief of local discomfort, itching, pain, soreness, or burning related to the tattoo process.

Warnings

For external use only.

Do not use

In children less than 2 months of age on open skin wounds. Do not exceed the recommended daily dosage unless directed by a doctor.

When Using

Avoid contact with eyes. If this happens, rinse thoroughly with water. If symptoms persist for more than 7 days or subside but occur again within 3 days, stop use and consult a physician.

Stop Use

Stop use and seek medical attention if signs of an allergy occur, such as redness, irritation, swelling, pain, or other severe symptoms. If symptoms do not subside completely within 7 days, seek medical help.

Ask Doctor

Stop use and seek medical attention if signs of an allergy occur, such as redness, irritation, swelling, pain, or other severe symptoms. If symptoms do not subside completely within 7 days, seek medical help.

Keep Out Of Reach Of Children

Keep out of reach of children.

Directions

Before applying the numbing cream, thoroughly wash your hands and wear disposable tattoo gloves.

Clean the area of the body receiving the tattoo. Dry completely.

Apply a generous amount of numbing cream to the cleaned area and rub it in thoroughly in a circular motion for 30 to 60 seconds. Then, cover with plastic wrap. Leave the cream and wrap in place for 30 to 45 minutes. Wipe away the cream and thoroughly clean the area to prepare for a pain-free tattoo.

Other information

Store between 15-30°C(59-86 F). Avoid freezing and excessive heat above 40 °C(104°F).

Inactive ingredients

Water, Carbomer 934, Propylene Glycol, Soybean Lecithin, Alpha-Tocopherol Acetate, Benzyl Alcohol.

PRINCIPAL DISPLAY PANEL





Active ingredient......Purpose
Tolnaftate 1%......Antifunga
Uses
Cures most Athlete's Foot (Tinea Pedis)

and Ringworm (Tinea Corporis). Relieves itching, scaling, cracking, burning, redness, sorenes, and irritation and discomfort. Helps prevent most athlete's foot (dermatophytosis) with daily use. Warnings For external use only.

Do not use on children under 2 years of age unless directed by a doctor.

When using this product, avoid contact with eyes.

Stop use and ask a doctor if irritation occurs, there is no improvement

irritation occurs, there is no improvement within 4 weeks (for athlete's foot and ringworm).

Keep out of reach of children. If

swallowed, get medical help or contact a Poison Control Center right away.

Directions For athlete's foot and ring worm: use daily for 4 weeks. Clean the affected area and dry thoroughly.

Directions For athlete's foot and ring worm: use daily for 4 weeks. Cleathe affected area and dry thoroughly. Apply a thin layer of the product over affected area twice daily (morning and night) or









SYLVIRENE TATTOO NUMBING

lidocaine4% tattoo numbing cream

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:84010-080

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE (LINII: 98PI200987) (LIDOCAINE - LINII: 98PI200987)	LIDOCAINE	4 a in 100 a

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CARBOMER 934 (UNII: Z135WT9208)	
SOYBEAN LECITHIN (UNII: 1DI56QDM62)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	

l	P	Packaging			
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:84010-080- 01	20 g in 1 TUBE; Type 0: Not a Combination Product	02/21/2025	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	02/21/2025	

Labeler - Jiangxi Hemei Pharmaceutical Co., Ltd (724892056)

Establishment				
Name	Address	ID/FEI	Business Operations	
Jiangxi Hemei Pharmaceutical Co., Ltd		724892056	manufacture(84010-080)	

Revised: 3/2025 Jiangxi Hemei Pharmaceutical Co., Ltd