

KAISASA TATTOO NUMBING- lidocaine cream
Shenzhen Langmi Technology Co., Ltd.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Active Ingredient(s)

Lidocaine 5%

Purpose

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

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

Do not exceed the recommended daily dosage unless directed by a doctor.

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 and get to a doctor if allergy occurs such as redness, irritation, swelling, pain or other symptoms become severe or does not subside completely within 7 days.

Keep out of reach of children.

Directions

1. Clean the specific area, then dry.
2. Apply cream to the area to be tattooed with a thick coat (near 2mm) . Wrap the applied area tightly with plastic wrap and wait for 45~65 minutes.
3. Tear off the plastic wrap, wipe off cream, wait for 25 minutes more to start your tattoo work.

Storage and handling

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

Inactive ingredients

WATER,PROPYLENE GLYCOL,GLYCERIN,CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE,EDETATE DISODIUM ANHYDROUS, HYDROXYACETOPHENONE,1,2-HEXANEDIOL,Tocopherol,MENTHAARVENSIS LEAF,CHRYSANTHELLUM INDICUM TOP, PURSLANE,POLYOXYL40 HYDROGENATED CASTOR OIL

Package Label - Principal Display Panel



KAISASA TATTOO NUMBING

lidocaine cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83603-002
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			

Ingredient Name		Basis of Strength	Strength	
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)		LIDOCAINE	5 g in 100 g	
Inactive Ingredients				
Ingredient Name			Strength	
WATER (UNII: 059QF0KO0R)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
GLYCERIN (UNII: PDC6A3C0OX)				
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)				
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)				
HYDROXYACETOPHENONE (UNII: G1L3HT4CMH)				
1,2-HEXANEDIOL (UNII: TR046Y3K1G)				
TOCOPHEROL (UNII: R0ZB2556P8)				
MENTHA ARVENSIS LEAF (UNII: A4IWO4DDZ9)				
CHRYSANTHELLUM INDICUM TOP (UNII: STJ856D1Z0)				
PURSLANE (UNII: M6S840WVG5)				
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83603-002-01	1 in 1 PACKAGE	08/07/2023	
1		60 g in 1 BOTTLE; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final		M017	08/07/2023	

Labeler - Shenzhen Langmi Technology Co., Ltd. (636993410)

Establishment

Name	Address	ID/FEI	Business Operations
Shenzhen Langmi Technology Co., Ltd.		636993410	manufacture(83603-002)

Revised: 8/2023

Shenzhen Langmi Technology Co., Ltd.