

ADELLINA TATTOO NUMBING- lidocaine cream

Aramode

Active Ingredient(s)

Lidocaine 5% g/g. Purpose: Local Anesthetic

Purpose

Local Anesthetic

Use

For the physical or local anesthesia associated with tattoo

Warnings

For external use only. Avoid contact with the eyes. Keep away from heat or flame. Do not use in large quantities, particularly over raw surfaces or blistered areas.

Do not use

- Do not use if Pregnant or breastfeeding, ask a health professional before use. In case of accidental overdose, get medical help or contact the Poison Control Center immediately. Seal is broken or missing.

When using this product

When using this product do not exceed the recommended daily dosage unless directed by a doctor. certain persons can develop allergic reactions to ingredients in this product. do not put this product into the rectum by using finger.

Stop use and ask a doctor if

Stop use and ask a doctor if redness, irritation, swelling, pain, or other symptoms occurs, or if condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days.

Keep out of reach of children

In case of accidental ingestion, seek medical help immediately.

Directions

Adults: Clean the affected area with mild soap and warm water and rinse

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)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
GLYCERIN (UNII: PDC6A3C0OX)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
HYDROXYACETOPHENONE (UNII: G1L3HT4CMH)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
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:83596-001-01	1 in 1 PACKAGE	07/28/2023	
1		50 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 Drug	M017	07/28/2023	

Labeler - Aramode (963192477)**Registrant** - Aramode (963192477)**Establishment**

Name	Address	ID/FEI	Business Operations
Aramode		963192477	manufacture(83596-001)