

# **ADELLINA TATTOO NUMBING- lidocaine cream**

## **Aramode**

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### **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

thoroughly.Gently dry by patting with toilet tissue or asoft cloth before application of this product.  
Children under 12 years of age: consult a doctor.

Storage and Handling:

- Keep away from direct sunlight or heat.  
Store at room temperature 15°-30°C(59-86°F).
- Protect from freezing.

Inactive ingredients

AQUA, Propylene glycol, Carbomer, Glycerin, Disodium edta,Hydroxyacetophenone,1,2-Hexanediol, Mentha Arvensis LeafExtract, Chrysanthellum Indicum Extract, Portulaca OleraceaExtract, PEG-40 hydrogenated castor oil

Package Label - Principal Display Panel



50g NDC: 83596-001-01

ADELLINA TATTOO NUMBING			
lidocaine cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83596-001
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)	
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)