

## **LIDOCAINE 4 PERCENT- lidocaine cream SA3, LLC**

*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.*

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### **Lidocaine 4 Percent Cream**

## **LIDOCAINE - Lidocaine HCl 4% Cream SA3, LLC**

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### **Lidocaine HCl 4% Topical Analgesic Cream**

#### **Drug Facts**

##### **Active ingredient**

Lidocaine HCl 4% w/w

##### **Purpose**

Topical Analgesic

##### **Uses**

Temporarily relieves pain and itching due to:

- minor cuts
- sunburn
- minor scrapes
- minor burns
- insect bites
- minor skin irritations

##### **Warnings**

**For external use only.**

##### **When using this product**

- **Avoid contact with the eyes**
- **Do not use** in large quantities, particularly over raw surfaces or blistered areas

**Stop use and ask a doctor**

- If condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days.
- If allergic reaction occurs or if redness, irritation, swelling, pain or other symptoms begin or increase.

**Keep out of reach of children.**

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

**Directions**

adults and children 2 years and older	apply externally to the affected area up to 3 to 4 times a day
children under 2 years	ask a doctor

**Other information**

- May be applied under occlusive dressing.
- Store at 20-25°C (68-77°F); excursions permitted to 15-30°C (59-86°F). See USP Controlled Room Temperature.

**Inactive ingredients**

Aqua (Deionized Water), Arnica Montana Flower Extract, Boswellia Serrata Extract, Cetearyl Alcohol, Chondroitin Sulfate, Dimethyl Sulfone (MSM), Ethylhexylglycerin, Glucosamine Sulfate, Glycerin, Glyceryl Stearate, C13-14 Isoparaffin, Isostearyl Palmitate, Laureth-7, PEG-100 Stearate, Phenoxyethanol, Polyacrylamide, Propylene Glycol, Sodium Polyacrylate, Stearic Acid, Triethanolamine.

**PRINCIPAL DISPLAY PANEL****Lidocaine HCl 4% cream**

NDC 69420-6262-1

Topical Analgesic Cream

**4.2 OZ (120 g)**

SA3, LLC

NDC: 69420-6262-1

**LIDOCAINE 4%**  
 Topical Analgesic Cream

Net WT. 4.2 OZ (120 g)

Manufactured for: SA3, LLC  
 Los Angeles, CA 90064  
 Tel: 888.495.6078

**Drug Facts**

**Active Ingredient** **Purpose**  
 Lidocaine HCl 4% w/w.....Topical Analgesic

**Uses**  
 ■ Temporarily relieves pain and itching due to:  
 - Minor cuts  
 - Sunburn  
 - Minor scrapes  
 - Minor burns  
 - Insect bites  
 - Minor skin irritations

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**Drug Facts (continued)**

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**LIDOCAINE 4 PERCENT**

lidocaine cream

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69420-6262
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>LIDOCAINE HYDROCHLORIDE</b> (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	4 g in 100 g

**Inactive Ingredients**

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>ARNICA MONTANA FLOWER</b> (UNII: OZ0E5Y15PZ)	
<b>INDIAN FRANKINCENSE</b> (UNII: 4PW41QCO2M)	
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>GLUCOSAMINE SULFATE</b> (UNII: 1FW7WLR731)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	

<b>C13-14 ISOPARAFFIN</b> (UNII: E4F12ROE70)
<b>ISOSTEARYL PALMITATE</b> (UNII: 9EHU0R7ER1)
<b>LAURETH-7</b> (UNII: Z95S6G8201)
<b>PEG-100 STEARATE</b> (UNII: YD01N1999R)
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)
<b>CHONDROITIN SULFATE (BOVINE)</b> (UNII: 6IC1M3OG5Z)
<b>DIMETHYL SULFONE</b> (UNII: 9H4PO4Z4FT)
<b>POLYACRYLAMIDE (10000 MW)</b> (UNII: E2KR9C9V2I)
<b>SODIUM POLYACRYLATE (2500000 MW)</b> (UNII: 05I15JN12J)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69420-6262-1	120 g in 1 TUBE; Type 0: Not a Combination Product	06/01/2022	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	06/01/2022	

**Labeler - SA3, LLC (079627454)**

Revised: 5/2022

SA3, LLC