

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

Lidocaine 4 Percent Cream

**LIDOCAINE - Lidocaine HCl 4% 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.

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

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LIDOCAINE 4 PERCENT

lidocaine cream

Product Information

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

Active Ingredient/Active Moiety

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

Inactive Ingredients

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

C13-14 ISOPARAFFIN (UNII: E4F12ROE70)
ISOSTEARYL PALMITATE (UNII: 9EHU0R7ER1)
LAURETH-7 (UNII: Z95S6G8201)
PEG-100 STEARATE (UNII: YD01N1999R)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
STEARIC ACID (UNII: 4ELV7Z65AP)
TROLAMINE (UNII: 9O3K93S3TK)
CHONDROITIN SULFATE (BOVINE) (UNII: 6IC1M3OG5Z)
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)
POLYACRYLAMIDE (10000 MW) (UNII: E2KR9C9V2I)
SODIUM POLYACRYLATE (2500000 MW) (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 Drug	M017	06/01/2022	

Labeler - SA3, LLC (079627454)

Revised: 12/2024

SA3, LLC