

## **LIDOCAINE 4 PERCENT PLUS- lidocaine cream**

**Alexso, Inc.**

*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 PLUS Cream**

#### **Active ingredient**

Lidocaine HCl 4% w/w

#### **Purpose**

Topical anesthetic

#### **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**

- do not use in or near the eyes
- do not use in large quantities, particularly over raw surfaces or blistered areas

#### **Stop use and ask a doctor if**

- allergic reaction occurs
- condition worsens or does not improve within 7 days
- symptoms clear up and return within a few days
- 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**

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

**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, Ethylhexylglycerin, Glucosamine Sulfate, Glycerin, Glyceryl Stearate, Isostearyl Palmitate, Magnesium Sulfate, Methylsulfonylmethane (MSM), PEG-100 Stearate, Phenoxyethanol, Propylene Glycol, Sodium Polyacrylate, Stearic Acid, Triethanolamine.

**PRINCIPAL DISPLAY PANEL**

NDC 50488-6263-1

**Lidocaine 4% PLUS Cream**

**120 grams**

**Manufactured for:** Alexso, Inc.  
 2317 Cotner Avenue Los Angeles, CA 90064  
**Tel: 888.495.6078 Web: www.alexso.com**


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Drug Facts	
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<ul style="list-style-type: none"> <li>- minor cuts</li> <li>- sunburn</li> <li>- minor scrapes</li> <li>- minor burns</li> <li>- insect bites</li> <li>- minor skin irritations</li> </ul>	
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<p><b>Keep out of the reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.</p>	

Drug Facts (continued)	
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	
<ul style="list-style-type: none"> <li>- May be applied under occlusive dressing.</li> <li>- Store at 20-25°C (68-77°F); excursions permitted to 15-30°C (59-86°F). See USP Controlled Room Temperature.</li> </ul>	
Inactive ingredients	
Aqua (Deionized Water), Arnica Montana Flower Extract, Boswellia Serrata Extract, Cetearyl Alcohol, Chondroitin Sulfate, Ethylhexylglycerin, Glucosamine Sulfate, Glycerin, Glyceryl Stearate, Isostearyl Palmitate, Magnesium Sulfate, Methylsulfonylmethane (MSM), PEG-100 Stearate, Phenoxyethanol, Propylene Glycol, Sodium Polyacrylate, Stearic Acid, Triethanolamine.	



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New Formulation with Magnesium Sulfate!

## Label

**LIDOCAINE 4 PERCENT PLUS**

lidocaine cream

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:50488-6263
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
WATER (UNII: 059QF0KO0R)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
INDIAN FRANKINCENSE (UNII: 4PW41QCO2M)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CHONDROITIN SULFATE (BOVINE) (UNII: 6IC1M3OG5Z)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLUCOSAMINE SULFATE (UNII: 1FW7WLR731)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
ISOSTEARYL PALMITATE (UNII: 9EHU0R7ER1)	
MAGNESIUM SULFATE, UNSPECIFIED FORM (UNII: DE08037SAB)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
PEG-100 STEARATE (UNII: YD01N1999R)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM POLYACRYLATE (250000 MW) (UNII: 05115JN12J)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TROLAMINE (UNII: 9O3K93S3TK)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50488-6263-1	1 in 1 CARTON	10/01/2018	
1		120 g in 1 TUBE; Type 0: Not a Combination Product		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	10/01/2018	

