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.

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

IFor 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

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

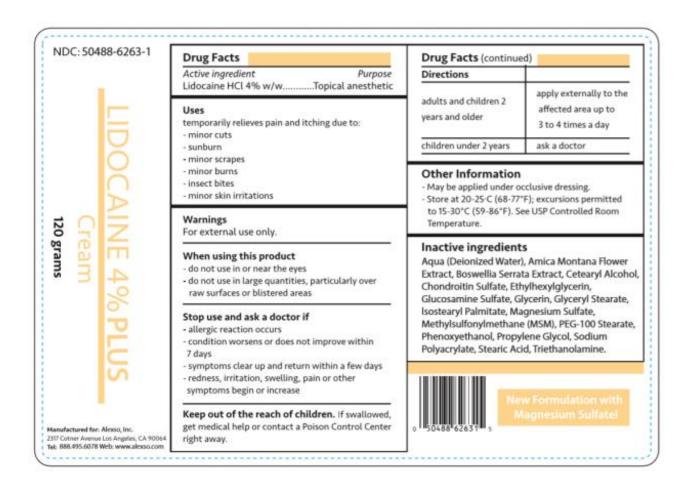
NDC 50488-6263-1

Lidocaine 4% PLUS Cream

120 grams

Manufactured for: Alexso, Inc.

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LIDOCAINE 4 PERCENT PLUS

lidocaine cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50488-6263
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
LIDO CAINE (UNII: 98PI200987) (LIDO CAINE - UNII:98PI200987)	LIDOCAINE	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)	
CHONDROITIN SULFATE (BOVINE) (UNII: 6IC1M3OG5Z)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLUCO SAMINE SULFATE (UNII: 1FW7WLR731)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230 OU9 XXE4)	
ISOSTEARYL PALMITATE (UNII: 9EHU0R7ER1)	
MAGNESIUM SULFATE, UNSPECIFIED FORM (UNII: DE08037SAB)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
PEG-100 STEARATE (UNII: YD01N1999R)	
PHENO XYETHANO L (UNII: HIE 49 2 Z Z 3 T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05115JN12J)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TROLAMINE (UNII: 903K93S3TK)	

F	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:50488-6263-1	1 in 1 CARTON	10 /0 1/20 18		
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			

Labeler - Alexso, Inc. (963338061)

Revised: 2/2019 Alexso, Inc.