LIDOCAINE 4 PERCENT AND MENTHOL 1 PERCENT ROLL-ON- lidocaine and menthol liquid
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 and Menthol Roll-On

LIDOCAINE AND MENTHOL - Lidocaine 4% and Menthol 1% Roll-On
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Lidocaine 4% and Menthol 1% Roll-On

Drug Facts

Active ingredient

Lidocaine 4%
Menthol 1%

Purpose

Topical anesthetic
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
- do not apply to wounds or damaged skin
- do not bandage

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

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	do not use except under the advice and supervision of a physician

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

Glycerin, Borneol, Arnica Montana Flower Extract, Polyethylene Glycol (PEG), Frankincense Oil, Boswellia Extract, Methylsulfonylmethane (MSM), Chondroitin Sulfate, Glucosamine Sulfate, Water

PRINCIPAL DISPLAY PANEL

Lidocaine 4% and Menthol 1% Roll-On

NDC 50488-6541-1

50 mL

Manufactured for:
Alexso, Inc.
Los Angeles, CA 90064

LIDOCAINE 4 PERCENT AND MENTHOL 1 PERCENT ROLL-ON

lidocaine and menthol liquid

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50488-6541
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	2 g in 50 mL
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.5 g in 50 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
BORNEOL (UNII: M89NIB437X)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
FRANKINCENSE OIL (UNII: 67ZYA5T02K)	
BOSWELLIA SACRA WHOLE (UNII: 8O600AZL0W)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
CHONDROITIN SULFATE (BOVINE) (UNII: 6IC1M3OG5Z)	
GLUCOSAMINE SULFATE (UNII: 1FW7WLR731)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50488-6541-1	50 mL in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product	02/17/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part348	02/17/2021	

Labeler - Alexso, Inc (963338061)

Revised: 2/2021 Alexso, Inc