LIDOCAINE AND MENTHOL- lidocaine, menthol gel
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 Gel

LIDOCAINE AND MENTHOL - Lidocaine 4% and Menthol 1% Gel
Alexso, Inc

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Lidocaine 4% and Menthol 1% Gel

Drug Facts

Active ingredient

Purpose

Lidocaine 4% .....Topical anesthetic
Menthol 1% .....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

- 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

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aloe Barbadensis Leaf (Aloe Vera Gel) Juice, Aqua (Deionized Water), Arnica Montana Flower Extract, Boswellia Serrata Extract, Ethylhexylglycerin, Glucosamine Sulfate, Ilex Paraguariensis (Yerba Mate') Extract, Magnesium Sulfate, Methylsulfonylmethane (MSM), Phenoxyethanol, Polysorbate-20, Triethanolamine, Zemea (Corn) Propanediol

Lidocaine 4% and Menthol 1% Gel

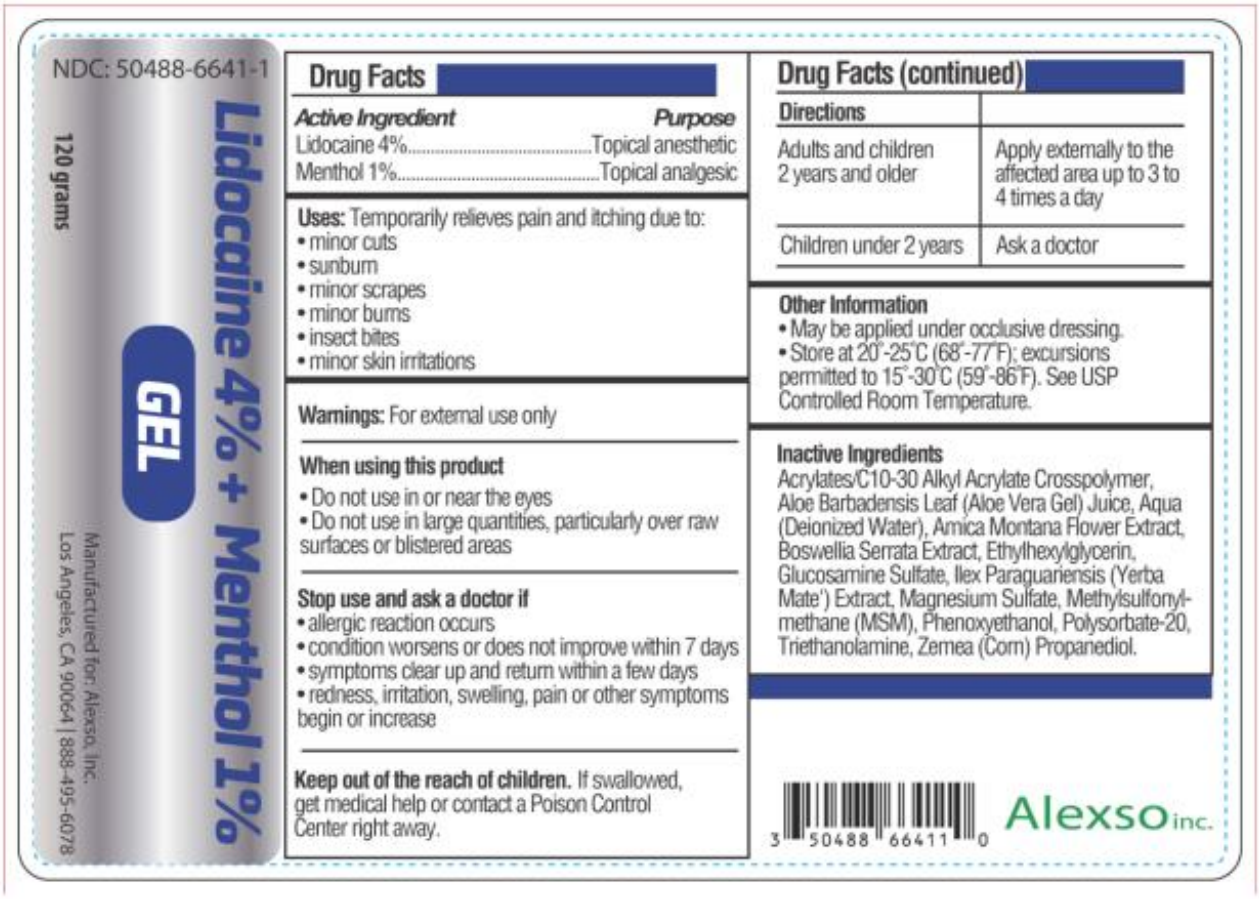
NDC 50488-6641-1

120 grams

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

PRINCIPAL DISPLAY PANEL

NDC 50488-6641-1
Lidocaine 4% + Menthol 1%
120 grams



LIDOCAINE AND MENTHOL

lidocaine, menthol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50488-6641
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	4.8 g in 120 g
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	1.2 g in 120 g

Inactive Ingredients	
Ingredient Name	**Strength**
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0KO0R)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
INDIAN FRANKINCENSE (UNII: 4PW41QCO2M)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLUCOSAMINE SULFATE (UNII: 1FW7WLR731)	

ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)	
MAGNESIUM SULFATE, UNSPECIFIED (UNII: DE08037SAB)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
TROLAMINE (UNII: 9O3K93S3TK)	
CORN (UNII: 0N8672707O)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50488-6641-1	120 g in 1 TUBE; 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