

LIDOCAINE HCL 4 PERCENT AND MENTHOL 4 PERCENT - lidocaine hcl and menthol spray
7T Pharma 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 and Menthol Topical Spray

LIDOCAINE AND MENTHOL - Lidocaine HCl 4% and Menthol 4% topical spray
7T Pharma, LLC

Lidocaine 4% and Menthol 4% Topical Spray

Drug Facts

Active ingredient

Lidocaine HCl 4%

Menthol 4%

Purpose

Topical anesthetic

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

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	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

Aloe Barbadensis Leaf (Aloe Vera Gel) Juice, Aqua (Deionized Water), Arnica Montana Flower Extract, Boswellia Serrata Extract, Cetyl Myristoleate, Ethylhexylglycerin, Glycyrrhiza Glabra (Licorice) Extract, Ilex Paraguaiensis (Yerba Mate) Extract, Magnesium Sulfate, Methylsulfonylmethane (MSM), Phenoxyethanol, Polysorbate-20, SD-Alcohol 40B

Lidocaine 4% and Menthol 4% Topical Spray

NDC 70645-263-11

4 fl oz (118mL)

Manufactured for:
7T Pharma, LLC
Los Angeles, CA 90064

PRINCIPAL DISPLAY PANEL

NDC 70645-263-11
LIDOCAINE 4%
AND
MENTHOL 4%
topical spray
4 Fl oz. (118 mL)

NDC: 70645-263-11

**LIDOCAINE 4%
AND
MENTHOL 4%**
Topical Spray

4 FL OZ. (118 mL)

Manufactured for: 7T Pharma, LLC
2317 Cotner Avenue Los Angeles, CA 90064
Tel: 800.941.2848

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Drug Facts (continued)

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lidocaine hcl and menthol spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70645-263
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 mL
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	4 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0KO0R)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
INDIAN FRANKINCENSE (UNII: 4PW41QCO2M)	

CETYL MYRISTOLEATE (UNII: 87P8K33Q5X)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLYCYRRHIZA GLABRA (UNII: 2788Z9758H)	
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)	
MAGNESIUM SULFATE, UNSPECIFIED (UNII: DE08037SAB)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
ALCOHOL (UNII: 3K9958V90M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70645-263-11	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part348	06/01/2018	

Labeler - 7T Pharma LLC (080220022)

Revised: 6/2018

7T Pharma LLC