

TOPICAL PAIN RELIEF- lidocaine hcl liquid
LEON MEDICAL CENTERS, 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 HCl, USP 4%

Topical Anesthetic

Use

☐ Temporarily relieves minor pains

Warnings

For external use only

☐ **Do not use**

- on large areas of the body or on cut, irritated, or swollen skin
- on puncture wounds
- for more than one week without consulting a doctor

☐ **When using this product**

- ☐ use only as directed. Read and follow all directions and warnings on this label
- do not allow contact with eyes
- do not handage or apply local heat (such as heating pads) to the area of use.

☐ **Stop use and ask a doctor if**

- condition worsens
- symptoms persist for more than 7 days or clear up and occur again within a few days

If pregnant or breast-feeding, ask a doctor before use.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

☐ **Directions**

- Adults and children over 12 years of age
- Apply generously to the affected area as needed every 6-8 hours, not to exceed 3 application in a 24 hour period.
- Not for use in children under 12 years of age

☐ **Inactive ingredients**

☐ camphor, glycerin, isopropyl alcohol, menthol, methylparaben, propylparaben, purified water and xantham gum.

ROLL-ON LIQUID

NDC 89076-1095-7

TOPICAL PAIN RELIEF

- ▶ Maximum Strength
- ▶ Easy to Apply
- ▶ In a menthol-camphor base

Contents: 2 fl oz (60 mL)



Drug Facts

Active Ingredient	Purpose
Lidocaine HCl, USP 4%.....	Topical Anesthetic

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Distributed by: Leon Medical Centers
Miami, FL 33156

Code# L-74 Rev. 06/18

For lot number and expiration date, see top of cap.



TOPICAL PAIN RELIEF

lidocaine hcl liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:89076-1095
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE	4 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
MENTHOL (UNII: L7T10EIP3A)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:89076-1095-7	60 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 - LEON MEDICAL CENTERS, INC (947237210)

Revised: 7/2018

LEON MEDICAL CENTERS, INC