LIDONEX- lidocaine hcl, menthol liquid
Aldama Pharmaceuticals, Inc

Lidonex Roll-On Liquid

Active Ingredient

Lidocaine HCL, USP 4%

Menthol USP 5%

Purpose

Topical Anesthetic

Pain Relieving

Use

For temporarily relief of pain

Warnings

For external use only

Flammable: Keep away from fire or flame

Do not use

- on wounds or damaged skin
- in large quantaties
- with a heating pad
- if you are allergic to any ingredients of this product

When using this product

- use only as directed.
- avoid contact with the eyes, mucous membranes or rashes
- do not bandage tightly

Stop use and ask doctor if

- skin reactions occur, such as rash, itching, redness, irritation, pain, swelling and blistering
- condition worsens
- symptoms persist for more than 7 days
- symptoms clear up and occur again within a few days

If pregnant or breast-feeding. Ask a health professional 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 and over

- clean and dry affected area
- apply to affected area not more than 3 to 4 times daily

Children under 12 years of age: Consult a doctor

Inactive ingredients

glycerin, isopropyl alcohol, methylparaben, propylparaben, purified water, xanthan gum

- avoid storing prouct in direct sunlight
- prodect product from excessive moisture
- store with lid closed tightly

Questions or comments?(305) 592 - 9216 or info@aldamapharm.com

Lot#/Exp. Date

DRUG FACTS

Active Ingredients	*Purpose*
Lidocaine HCl, USP 4%	Topical Anesthetic
Menthol, USP 5%	Pain Relieving Roll On

Uses For temporary relief of pain

Warnings

For external use only

Flammable: Keep away from fire or flame

Do not use

■ on wounds or damaged skin ■ in large quantities ■ with a heating pad ■ if you are allergic to any ingredients of this product

When using this product

■ use only as directed ■ avoid contact with the eyes, mucous membranes or rashes ■ do not use bandage tightly

Stop use and ask a doctor if

■ skin reactions occur, such as rash, itching, redness, irritation, pain, swelling and blistering ■ condition worsens ■ symptoms persist for more than 7 days ■ symptoms clear up and occur again within a few days

If pregnant or breast-feeding. Ask a health professional 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 12 years of age and over

■ clean and dry affected area ■ apply to affected area not more than 3 to 4 times daily

Children under 12 years of age: Consult a doctor

Other information

■ Avoid storing product in direct sunlight ■ Protect product from excessive moisture ■ Store with lid closed tightly

Inactive Ingredients

glycerin, isopropyl alcohol, methylparaben, propylparaben, purified water, xanthan gum

Questions or comments? (305)592-9216 or info@aldamapharm.com

Code#: L-5 Rev.:05/2025

LIDONEX

lidocaine hcl, menthol liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:73564-804
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	5 g

MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	in 100 mL
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	4 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
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:73564-804-02	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	06/01/2025	

Labeler - Aldama Pharmaceuticals, Inc (119484030)

Establishment

Name	Address	ID/FEI	Business Operations
Aldama Pharmaceuticals, Inc		119484030	manufacture(73564-804)

Revised: 10/2025 Aldama Pharmaceuticals, Inc