

NEOLINN- lidocaine, menthol patch
REMY Biosciences, 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.

NEOLINN Topical Pain Patch

Drug Facts

Active Ingredients:

Menthol 4%

Lidocaine 4%

Purpose:

MentholTopical Analgesic

LidocaineTopical Anesthetic

Uses:

Temporarily relieves minor aches and muscle pains associated with arthritis, simple backache, strains, muscle soreness and stiffness.

Warnings

- For external use only. Use only as directed by your healthcare professional.
- Do not use: On open wounds, cuts, damaged or infected skin, or in the eyes, mouth, genitals, or any other mucous membrane.
- Do not cover with tape or bandage.
- **Keep out of reach of children.** Consult physician for children under 12.
- Consult your physician if pregnant or pain persists or worsens.

Directions:

Adults and children 12 years and over: Apply patch to affected area 1 to 2 times daily or as directed.

Instructions for use:

- Clean and dry the affected area
- Open one single-use pouch
- Remove patch and then remove clear film from patch surface
- Apply patch directly to the affected area of pain
- Wash hands with soap and water after applying patch

Other Ingredients:

Pressure Sensitive Adhesive, Cannabidiol (Hemp Extract), Diethylene Glycol Monoethyl Ether, Vitamin C [as Ascorbyl Palmitate]

Package Labeling

NEOLINN

TOPICAL PAIN PATCH

Lidocaine 4%

Qty: 30 Patches

Menthol 4%

Individually Packaged

Single Use

Lot#

NDC 81816-001-30

Exp. Date

Store in a dry, cool place.

For comments or questions, contact us at: support@neolinn.com

Manufactured for Neolinn, LLC by Remy Biosciences

17802 Sky Park Circle

Ste. 100

Irvine, CA 92614

Box



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Exp. Date: [REDACTED]

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US Patents 9,962,340, 10,272,125, 10,588,869, and 10,821,084
Global Patents Pending

Pouch



NEOLINN

TOPICAL PAIN PATCH

Lidocaine 4%

Menthol 4%

NDC 81816-001-01

res

NEOLINN

lidocaine, menthol patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81816-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	12 mg in 300 mg
LEVOMENTHOL (UNII: BZ1R15MTK7) (LEVOMENTHOL - UNII:BZ1R15MTK7)	LEVOMENTHOL	12 mg in 300 mg

Inactive Ingredients

Ingredient Name	Strength
CANNABIDIOL (UNII: 19GBJ60SN5)	
DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A18X02B)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
TRIMETHYLSILYL TREATED DIMETHICONOL/TRIMETHYLSILOXYSILICATE CROSSPOLYMER (45/55 W/W; 100000 PA.S) (UNII: 5VBE2X0WG0)	
TRIMETHYLSILYL TREATED DIMETHICONOL/TRIMETHYLSILOXYSILICATE CROSSPOLYMER (40/60 W/W; 500000 PA.S) (UNII: 9N5G1G3D3H)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81816-001-30	30 in 1 BOX	04/30/2021	
1	NDC:81816-001-01	1 in 1 POUCH		
1		300 mg in 1 PATCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	04/30/2021	

Labeler - REMY Biosciences, Inc. (117812858)

Registrant - REMY Biosciences, Inc. (117812858)

Establishment

Name	Address	ID/FEI	Business Operations
Blaine Labs Inc		017314571	manufacture(81816-001)

Revised: 6/2021

REMY Biosciences, Inc.