LIDOPRO PATCH (LIDOCAINE 4%, MENTHOL 1%)- lidocaine and menthol patch patch
Advanced Rx of Tennessee, LLC

LidoPro Patch

Active ingredient

Lidocaine 4%

Menthol 1%

Purpose

External Anesthetic

External Analgesic

Uses

For the temporary relief of pain.

Warnings

For external use only.

Do not use

- on the face or rashes, on wounds or damaged skin
- in the eyes, mouth, or other mucous membranes
- on genitals
- with a heating pad
- right before or after heart surgery
- any patch from a pouch that has been opened for 7 or more days
- in large quantities, particularly over raw surfaces or blistered areas
- if tamper-evident seal is torn, broken, or missing
- more than 2 patches per day unless directed by a doctor
- children under 18 years of age

Ask a doctor before use if you have

- allergies to topical products
- high blood pressure, heart disease, or kidney disease

When using this product

- Avoid contact with eyes. If eye contact occurs, rinse thoroughly with water.
- The risk of heart attack or stroke may increase if you use more than directed or for longer than directed.

Stop use and ask doctor if

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

If pregnant of breast-feeding, ask a health professional before use

Do not use during last 3 months of pregnancy because it may cause problems in the unborn child or complications during delivery.

Keep out of reach of children.

If put in mouth, seek medical help or contact a Poison Control Center right away.
Dispose if the used patches by folding sticky ends together.

Directions

Adults 18 years and older:

- clean and dry affected area
- open pouch and remove one patch
- remove protective film from patch
- apply one patch to the affected area of pain and leave in place for 8 to 12 hours

Other information

- Some individuals may not experience pain relief until several minutes or hours after applying the patch
- avoid storing product in direct sunlight
- protect product from excessive moisture
- store at 67-77ºF (19-25ºC)

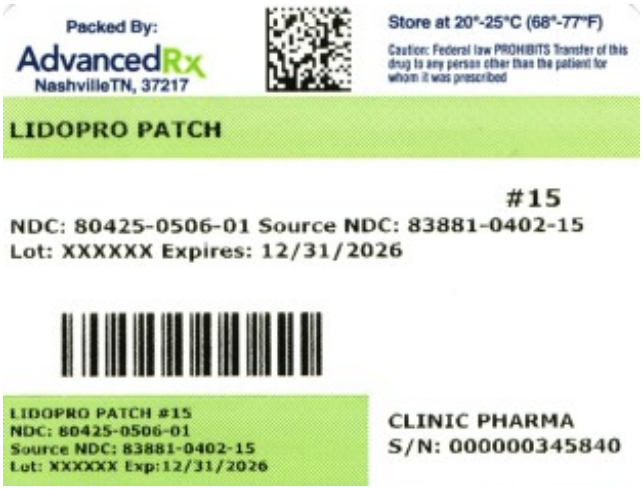
Inactive ingredients

Carboxymethylcellose sodium, Dihydroxyaluminum aminoacetate, Edetate sodium, Glycerin, Kaolin, Methyl parahydroxybenzoate, Partially neutralized Sodium polyacrylate, Polyacrylic acid, Polysorbate 80, Propyl parahydroxybenzoate, Propylene glycol, Sodium Polyacrylate, Tartaric acid, Titanium dioxide, water

Questions?

Call toll-free (800) 224-2048

PACKAGE LABEL PRINCIPAL DISPLAY PANEL



LIDOPRO PATCH (LIDOCAINE 4%, MENTHOL 1%)

lidocaine and menthol patch patch

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:80425-0506(NDC:83881-402)
Route of Administration	TRANSDERMAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	84 mg in 8400 mg
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	336 mg in 8400 mg

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	
TARTARIC ACID (UNII: W4888I119H)	
WATER (UNII: 059QF0KO0R)	
DIHYDROXYALUMINUM AMINOACETATE (UNII: DO250MG0W6)	
POLYACRYLIC ACID (8000 MW) (UNII: 73861X4K5F)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JNI2J)	
KAOLIN (UNII: 24H4NWX5CO)	
EDETATE SODIUM (UNII: MP1J8420LU)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
PROPANEDIOL (UNII: 5965N8W85T)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80425-0506-1	15 mg in 1 POUCH; Type 0: Not a Combination Product	03/20/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	03/20/2025	

Labeler - Advanced Rx of Tennessee, LLC (117023142)

Establishment

Name	Address	ID/FEI	Business Operations
Advanced Rx of Tennessee, LLC		117023142	repack(80425-0506)

Revised: 3/2025 Advanced Rx of Tennessee, LLC