LIDOPRO PATCH- lidocaine and menthol patch
Advanced Rx of Tennessee, LLC

LidoPro Patch

Drug Facts

Active Ingredient

Lidocaine 4%

Purpose

Topical Anesthetic

Active Ingredient

Menthol 1%

Purpose

Topical 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 consult a 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 orbreast 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 of 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

• if pain lasts after using the first patch, a second patch may be applied for up to another 8 to 12 hours

• only use one patch at a time

• wash hands with soap and water after applying or removing patch

• reseal pouch containing unused patches after each use

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 67-77°F (19-25°C)

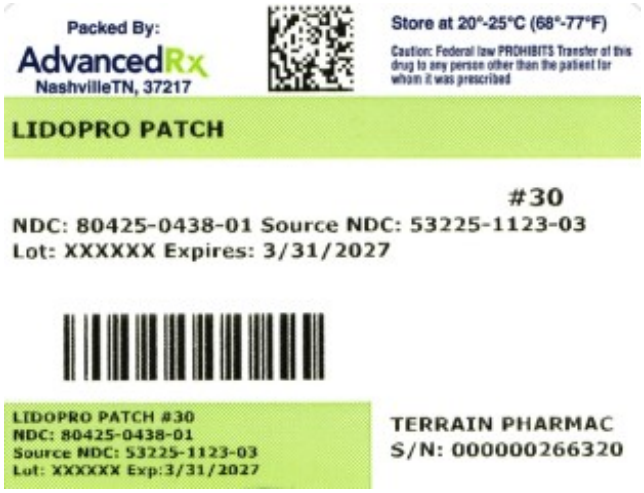
Inactive Ingredients

dihydroxyaluminum aminoacetate, glycerol, methylparaben, polysorbate 80, propylene glycol, sodium polyacrylate, tartaric acid, water

Questions?

877-985-8377

Principal Display Panel



LIDOPRO PATCH

lidocaine and menthol patch

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:80425-0438(NDC:53225-1123)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	4 mg in 100 mg
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	1 mg in 100 mg

Inactive Ingredients	
Ingredient Name	**Strength**
METHYLPARABEN (UNII: A2I8C7HI9T)	

DIHYDROXYALUMINUM AMINOACETATE (UNII: DO250MG0W6)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
WATER (UNII: 059QF0KO0R)	
TARTARIC ACID (UNII: W4888I119H)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80425-0438-1	6 in 1 BOX	09/09/2024	
1		5 in 1 POUCH		
1		8500 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 Drug	M017	09/09/2024	

Labeler - Advanced Rx of Tennessee, LLC (117023142)

Establishment

Name	Address	ID/FEI	Business Operations
Advanced Rx of Tennessee, LLC		117023142	repack(80425-0438)

Revised: 9/2024 Advanced Rx of Tennessee, LLC