

LIDOPRO PATCH- lidocaine, menthol, and methyl salicylate patch
medsource pharmaceuticals

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.

LidoPro Patch

Active Ingredient

Lidocaine 4%

Purpose

Topical Analgesic

Active Ingredient

Menthol 5%

Purpose

Topical Analgesic

Active Ingredient

Methyl Salicylate 4%

Purpose

Topical Analgesic

Uses

Temporarily relieves mild to moderate aches and pains of muscles and joints associated with:

- muscle soreness
- strains
- sprains
- arthritis
- simple backache
- muscle stiffness
- bruises

Warnings

For external use only

Stomach bleeding warning

This product contains an NSAID, which may cause stomach bleeding. The chance is small, but higher if

you

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take other drugs containing an NSAID (Aspirin, Ibuprofen, Naproxen, or others)
- take a blood thinning (anticoagulant) or steroid drug
- have three or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

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
- if allergic to any NSAIDS
- right before or after heart surgery
- any patch from a pouch that has been opened for 7 or more days

Ask a doctor before use if

- you are allergic to topical products
- the stomach bleeding warning applies to you
- you are taking a diuretic
- you have high blood pressure, heart disease, or kidney disease
- you are pregnant

When using this product

- wash hands after applying or removing patch
- 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 your physician if

- stomach pain or upset gets worse or lasts
- rash, irritation, or itching develops
- you feel faint, vomit blood, or have bloody or black stools (these are signs of stomach bleeding)
- condition worsens

If pregnant or breast feeding,

ask a doctor before use while breast feeding and during the first 6 months of pregnancy. 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, get medical help or contact a Poison Control Center right away. Package not child resistant. Dispose of the used patches by folding sticky ends together.

Directions

Adults 18 years and older:

- Apply patch to affected area 1 to 2 times daily or as directed.

Instructions for Use

- clean and dry affected area
- open pouch and remove one patch containing medical adhesive backing
- remove protective film from both patch and medical adhesive
- 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
- do not use more than 2 patches per day
- wash hands with soap and water after applying or removing patch
- reseal pouch containing unused patches after each use

Children under 18 years of age: Do not 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)

Acrylic Acid, Aluminum Hydroxide, Carmellose Sodium, 2-Ethylhexyl Acrylate, Glycerin, Isopropyl Myristate, Methyl Acrylate, Nonoxynol-30, Polyacrylic Acid, Polysorbate 80, Sodium Polyacrylate, Sorbitan Sesquioleate, Starch, Talc, Tartaric Acid, Titanium Dioxide, Water

Manufactured For:

Terrain Pharmaceuticals

Reno, NV 89501

Formulated and Designed in Nevada

Assembled in China

Patent Pending

LidoPro™ patch

For questions or comments, call

877-985-8377

Principal Display Panel



LIDOPRO PATCH

lidocaine, menthol, and methyl salicylate patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:45865-903(NDC:53225-1023)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	4 mg in 100 mg
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	5 mg in 100 mg
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	4 mg in 100 mg

Inactive Ingredients

Ingredient Name	Strength
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
2-ETHYLHEXYL ACRYLATE (UNII: HR49R9S6XG)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
METHYL ACRYLATE (UNII: WC487PR91H)	
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	
NONOXYNOL-30 (UNII: JJX07DG188)	
POLYACRYLIC ACID (250000 MW) (UNII: 9G2MAD7J6W)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
ACRYLIC ACID (UNII: J94PBK7X8S)	
SORBITAN SESQUIOLEATE (UNII: 0W8RRI5W5A)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TARTARIC ACID (UNII: W48881119H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:45865-903-01	15 in 1 CARTON	06/01/2018	
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 not final	part348	12/02/2014	

Labeler - medsource pharmaceuticals (833685915)

Establishment

Name	Address	ID/FEI	Business Operations
medsource pharmaceuticals		833685915	repack(45865-903)

Revised: 12/2018

medsource pharmaceuticals