LIDOPRO PATCH- lidocaine, menthol, and methyl salicylate patch
Preferred Pharmaceuticals 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.

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

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 89506

Formulated and Designed in Nevada

Assembled in China

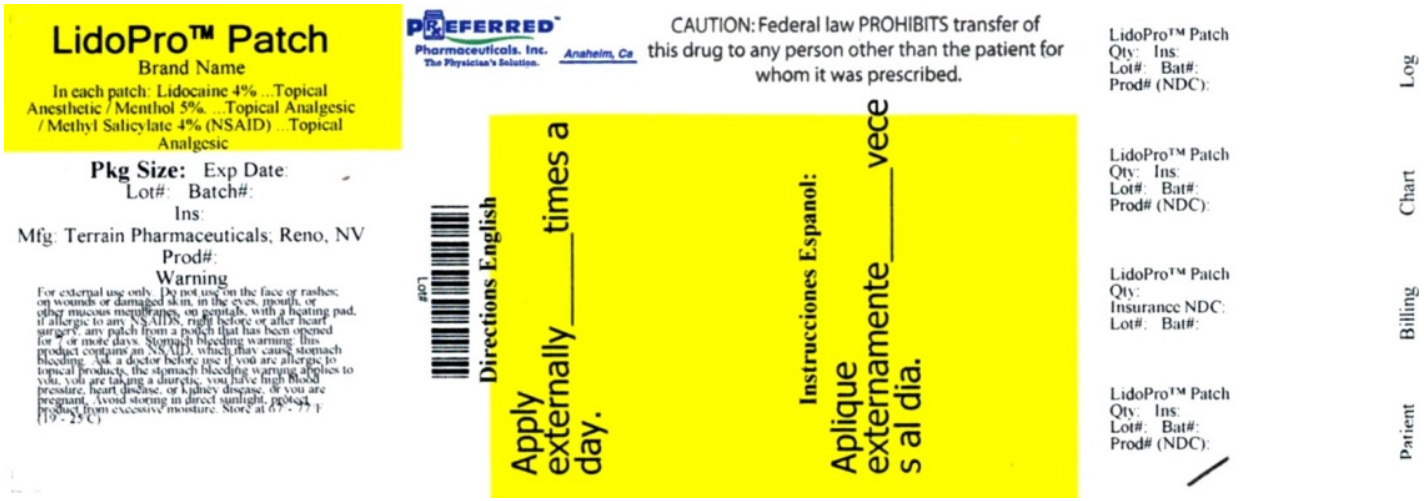
Patent Pending

LidoProTM patch

For questions or comments, call

877-985-8377

Repackaged By: Preferred Pharmaceuticals Inc.



LIDOPRO PATCH

lidocaine, menthol, and methyl salicylate patch

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68788-9975(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	.04
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	.05
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	.04

Inactive Ingredients	
Ingredient Name	**Strength**
ACRYLIC ACID (UNII: J94PBK7X8S)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (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)	
SORBITAN SESQUIOLEATE (UNII: 0W8RRI5W5A)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TARTARIC ACID (UNII: W4888I119H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:68788-9975-1	3 in 1 BOX	05/07/2015	
1		5 in 1 POUCH; 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	05/07/2015	

Labeler - Preferred Pharmaceuticals Inc. (791119022)

Registrant - Preferred Pharmaceuticals Inc (791119022)

Establishment

Name	Address	ID/FEI	Business Operations
Preferred Pharmaceuticals Inc		791119022	RELABEL(68788-9975)

Revised: 1/2017 Preferred Pharmaceuticals Inc.