

LIDOPRO- capsaicin, lidocaine, menthol, and methyl salicylate ointment
Preferred Pharmaceuticals Inc.

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

LidoPro 4% Ointment

Active Ingredient

Capsaicin 0.0325%

Purpose

Counterirritant

Active Ingredient

Lidocaine HCL 4%

Purpose

Topical Anesthetic

Active Ingredient

Menthol 10%

Purpose

Topical Analgesic

Active Ingredient

Methyl Salicylate 27.5%

Purpose

Counterirritant

Uses

For the temporary relief of joint pain and muscle pain associated with:

- Arthritis
- Simple Backache
- Muscle Sprains
- Muscle Strains

Warnings

For External Use Only

Do Not Use

- On damaged, irritated, or infected skin
- With a bandage or heating pad
- If you are allergic to any ingredients in this product

When Using This Product:

Avoid contact with eyes and mucus membranes

Stop Use and Ask a Doctor If:

- Conditions worsens
- Excessive skin irritation develops
- Symptoms persist for more than 7 days, or symptoms clear up and occur again within 3 days

If Pregnant or Breast-Feeding:

Ask a health professional before use.

Keep Out of Reach of Children:

If ingested seek medical help or contact a Poison Control Center immediately

Flammable:

Keep away from excessive heat or open flame

Directions

Adults and Children 12 Years of Age and Older:

- Clean and dry the affected area
- Apply product directly to your skin, up to 4 times daily affected area
- Wash hands immediately after use

Children Under 12 Years of Age: Consult physician

Other Information

- Store in a cool, dry place with lid tightly closed

- If the tamper-evident foil seal is not intact, do not use

Inactive Ingredients

Allantoin, Aloe Barbadensis Leaf Juice, Ammonium Acryloyldimethyltaurate/VP Copolymer, Cetyl Alcohol, Chamomilla Recutita Matricaria Flower Extract, Dimethicone, Disodium EDTA, Ethylhexylglycerin, Glycerin, Glyceryl Stearate, Inulin Lauryl Carbamate, PEG-100 Stearate, Phenoxyethanol, Stearic Acid, Triethanolamine, Water.

Questions or Comments?

info@terrainrx.com

Relabeled By: Preferred Pharmaceuticals Inc.

Principal Display Panel

NDC 53225-1020-1

Preferred Pharmaceuticals Inc. NDC 68788-8314-1

<p>LidoPro Topical Pain Relief Oint. & Applicator Brand Name</p> <p>Active Ingredients: Lidocaine 4% ...Topical Anesthetic / Menthol 10%...topical analgesic / Capsaicin 0.0325%...counterirritant / Methyl Salicylate 27.5%...counterirritant</p> <p>Pkg Size: Exp Date: Lot#: Batch#: Ins: Mfg: Terrain Pharmaceuticals; Reno, NV Prod#: Warning</p> <p><small>Store in a cool dry place. Keep away from excessive heat or open flame. For external use only. Do not use on open wounds, cuts, damaged or infected skin; with bandage or heating pad; if condition worsens or symptoms persist for more than 7 days; excessive skin irritation occurs. Avoid contact with eyes, genitals, and other mucous membranes. Keep out of the reach of children. If pregnant or breast-feeding, ask a health professional before use. Package not child-resistant.</small></p>	 <p>CAUTION: Federal law PROHIBITS transfer of this drug to any person other than the patient for whom it was prescribed</p>	<p>LidoPro Topical Pain Relief Oint. & Applicator Qty: Ins: Lot#: Bat#:</p> <p>Prod# (NDC):</p> <p>LidoPro Topical Pain Relief Oint. & Applicator Qty: Ins: Lot#: Bat#: Prod# (NDC):</p> <p>LidoPro Topical Pain Relief Oint. & Applicator Qty: Ins: Insurance NDC: Lot#: Bat#:</p> <p>LidoPro Topical Pain Relief Oint. & Applicator Qty: Ins: Lot#: Bat#: Prod# (NDC):</p>	<p>Log</p> <p>Chart</p> <p>Billing</p> <p>Patient</p>
<p>Directions English</p> <p>Apply externally _____ times a day.</p>		<p>Instrucciones Espanol:</p> <p>Aplique externamente _____ veces al dia.</p>	

LIDOPRO		
capsaicin, lidocaine, menthol, and methyl salicylate ointment		
Product Information		
Product Type	HUMAN OTC DRUG	Item Code (Source) NDC:68788-8314(NDC:53225-1020)
Route of Administration	TOPICAL	
Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
CAPSAICIN (UNII: S07O44R1Z M) (CAPSAICIN - UNII:S07O44R1Z M)	CAPSAICIN	0.000325 g in 1 g

LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	0.04 g in 1 g
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	0.1 g in 1 g
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	0.275 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
INULIN (UNII: JOS53KRJ01)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
ALLANTOIN (UNII: 344S277G0Z)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
AMMONIUM ACRYLOYLDIMETHYLAURATE/VP COPOLYMER (UNII: W59H9296ZG)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CHAMOMILE (UNII: FGL3685T2X)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68788-8314-1	92 g in 1 BOTTLE; Type 0: Not a Combination Product	07/08/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug other		07/08/2022	

Labeler - Preferred Pharmaceuticals Inc. (791119022)

Registrant - Preferred Pharmaceuticals Inc. (791119022)

Establishment

Name	Address	ID/FEI	Business Operations
Preferred Pharmaceuticals Inc.		791119022	RELABEL(68788-8314)

