LIDOPRO- capsaicin, lidocaine, menthol, and methyl salicylate ointment
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.

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 orBreast-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?

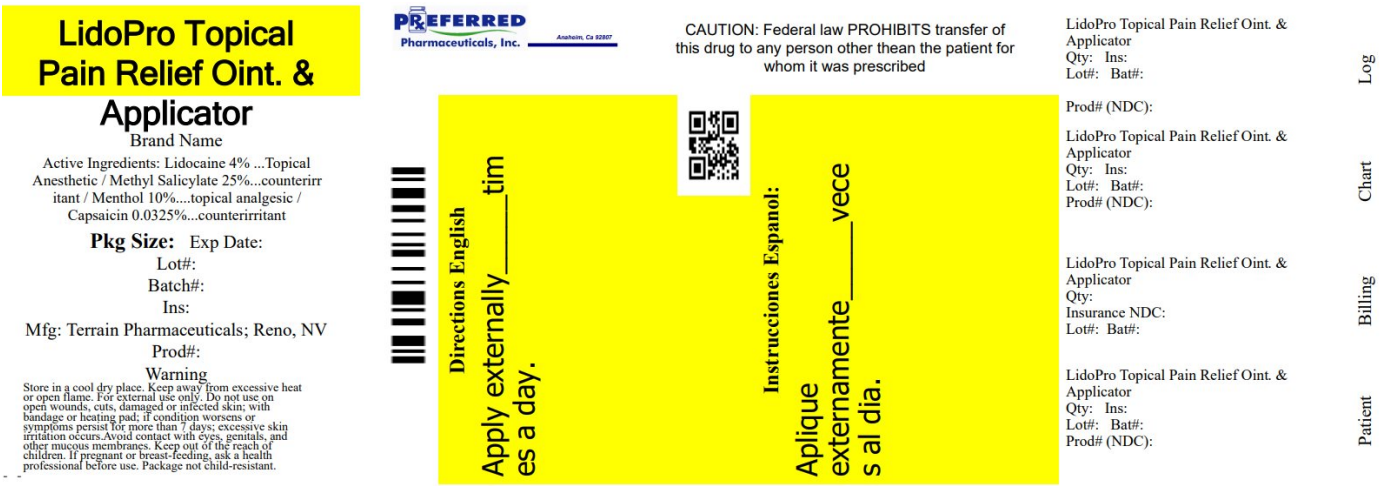
info@terrainrx.com

Relabeled By: Preferred Pharmaceuticals Inc.

Principal Display Panel

NDC 53225-1020-1

Preferred Pharmaceuticals Inc. NDC 68788-8314-1



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: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)	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 ACRYLOYLDIMETHYLTAURATE/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
OTC monograph not final	part348	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)