LIDOPRO- capsaicin, lidocaine, menthol, and methyl salicylate ointment
Advanced Rx Pharmacy of Tennessee, LLC

LidoPro 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

LidoPro Oinment is supplied as follows:

Ointent Tube of 92g NDC: 80425-0332-01

Principal Display Panel

LIDOPRO

capsaicin, lidocaine, menthol, and methyl salicylate ointment

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:80425-0332(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 (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	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:80425-0332-1	92 g in 1 BOTTLE; Type 0: Not a Combination Product	05/18/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	05/18/2023	

Labeler - Advanced Rx Pharmacy of Tennessee, LLC (117023142)

Establishment

Name	Address	ID/FEI	Business Operations
Advanced Rx Pharmacy of Tennessee, LLC		117023142	repack(80425-0332)

Revised: 12/2024 Advanced Rx Pharmacy of Tennessee, LLC