LIDOPRO PAIN RELIEF- capsaicin and lidocaine ointment
Advanced Rx of Tennessee, LLC

LidoPro Ointment 99gm

Active ingredient
- Capsicum annum fruit extract (capsaicin)
- Lidocaine HCL
- Menthol
- Methyl Salicylate

Purpose
- counterirritant
- anesthetic
- analgesic

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 the eyes and mucous membranes

Stop use and ask doctor if
- condition worsens
- excessive skin
- irritation develops
- symptoms persist for more than 7 days
- 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 skin, up to 4 times daily
- 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

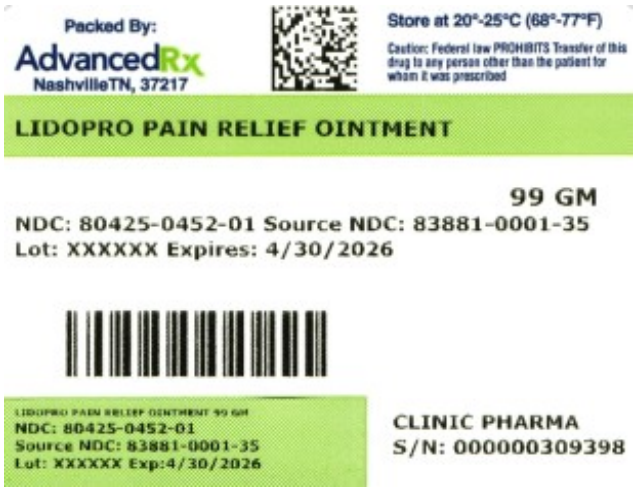
Inactive ingredient

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?

(800) 224-2048 or info@clinicpharma.com

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



LIDOPRO PAIN RELIEF

capsaicin and lidocaine ointment

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:80425-0452(NDC:83881-001)
Route of Administration	TRANSDERMAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL, (+)- (UNII: C6B1OE8P3W) (MENTHOL, (+)- - UNII:C6B1OE8P3W)	MENTHOL, (+)-	10 mg in 100 mg
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	4 mg in 100 mg
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	27.5 mg in 100 mg
CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)	CAPSAICIN	0.0325 mg in 100 mg

Inactive Ingredients

Ingredient Name	Strength
ALOE BARBADENSIS LEAF JUICE (UNII: ZY81Z83H0X)	
TRIETHANOLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	
MATRICARIA CHAMOMILLA (UNII: G0R4UBI2ZZ)	
AMMONIUM ACRYLOYLDIMETHYLTAURATE/VP COPOLYMER (UNII: W59H9296ZG)	
GLYCERYL STEARATE (UNII: 230OU9XXE4)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
PEG-100 STEARATE (UNII: YD01N1999R)	
ALLANTOIN (UNII: 344S277G0Z)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
INULIN LAURYL CARBAMATE (UNII: 48RFF58ESG)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80425-0452-1	1 in 1 BOX	11/26/2024	
1		9900 mg in 1 TUBE, WITH APPLICATOR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	11/26/2024	

Labeler - Advanced Rx of Tennessee, LLC (117023142)

Establishment

Name	Address	ID/FEI	Business Operations
Advanced Rx of Tennessee, LLC		117023142	repack(80425-0452)