

LIDOPRO- capsaicin, lidocaine, menthol, and methyl salicylate ointment
Medsource Pharmaceuticals

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.

TP05-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

Principal Display Panel

PACKAGED AND DISTRIBUTED BY: MEDSOURCE PHARMACEUTICALS, RANCHO SANTA MARGARITA CA
TEL. (888) 612-1965 CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION
KEEP OUT OF REACH OF CHILDREN. STORE AT CONTROLLED ROOM TEMP. 20-25°C (68-77°F)

**LIDOPRO PAIN RELIEF
TOPICAL OINTMENT 3.2**

LOT: _____
NDC: 45865-0232-1

UNIT DESCRIPTION: WHITE
EACH GM CONTAINS: CAPSAICIN .0325%, LIDOCAINE HCL 4%, MENTHOL 10%, METHYL SAL
MFR: TERRAIN PHARM. RENO, NV

FOR EXTERNAL USE ONLY.
APPLY TO AFFECTED AREA(S) _____ TIMES DAILY
DIRECTED BY PHYSICIAN.

IF
25 OZ.

LOT

EXP:

ICYCLATE 27.5%

#1

OR AS

LIDOPRO PAIN RELIEF TOPICAL OINTMENT
3.25 OZ.
1

lot# exp:
NDC: 45865-0232-1 MFR NDC: 53225-1020-01

LIDOPRO PAIN RELIEF TOPICAL OINTMENT
3.25 OZ.
1

lot# exp:
NDC: 45865-0232-1 MFR NDC: 53225-1020-01

LIDOPRO PAIN RELIEF TOPICAL OINTMENT
3.25 OZ.
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lot# exp:
NDC: 45865-0232-1 MFR NDC: 53225-1020-01

LIDOPRO PAIN RELIEF TOPICAL OINTMENT
3.25 OZ.
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lot# exp:
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LIDOPRO
capsaicin, lidocaine, menthol, and methyl salicylate ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:45865-232(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:45865-232-01	92 g in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product	11/30/2022	

Marketing Information

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

Labeler - Medsource Pharmaceuticals (833685915)

Registrant - Westwood Laboratories, LLC (832280635)

Establishment

Name	Address	ID/FEI	Business Operations
Medsource Pharmaceuticals		833685915	relabel(45865-232)

Revised: 3/2024

Medsource Pharmaceuticals