

LIDOPRO- capsaicin, lidocaine, menthol, and methyl salicylate ointment
Asclemed USA, Inc.

LidoPro 4%

Methemoglobinemia

Cases of methemoglobinemia have been reported in association with local anesthetic use. Although all patients are at risk for methemoglobinemia, patients with glucose-6-phosphate dehydrogenase deficiency, congenital or idiopathic methemoglobinemia, cardiac or pulmonary compromise, infants under 6 months of age, and concurrent exposure to oxidizing agents or their metabolites are more susceptible to developing clinical manifestations of the condition. If local anesthetics must be used in these patients, close monitoring for symptoms and signs of methemoglobinemia is recommended.

Signs and symptoms of methemoglobinemia may occur immediately or may be delayed some hours after exposure and are characterized by a cyanotic skin discoloration and abnormal coloration of the blood. Methemoglobin levels may continue to rise; therefore, immediate treatment is required to avert more serious central nervous system and cardiovascular adverse effects, including seizures, coma, arrhythmias, and death. Discontinue lidocaine-containing products and any other oxidizing agents. Depending on the severity of the symptoms, patients may respond to supportive care, i.e., oxygen therapy, hydration. More severe symptoms may require treatment with methylene blue, exchange transfusion, or hyperbaric oxygen.

Active Ingredient

Capsaicin 0.0325%

Purpose

Topical Analgesic

Active Ingredient

Lidocaine HCL 4%

Purpose

Topical Analgesic

Active Ingredient

Menthol 10%

Purpose

Topical Analgesic

Active Ingredient

Methyl Salicylate 27.5%

Purpose

Topical Analgesic

Uses:

Temporarily relieves minor aches and muscles pains associated with:

- arthritis
- simple back pain
- strains
- muscle soreness

Warnings

For external use only

Do not use

- on open wounds, cuts, damaged or infected skin
- with bandage or a heating pad
- if condition worsens or symptoms persists for more than 7 days
- excessive skin irritation occurs

Ask a doctor before use if

- you are allergic to any ingredients, PABA, aspirin products or sulfa

When using this product

- avoid contact with eyes, genitals, and other mucus membranes. If eye contact occurs, rinse thoroughly with water.

If pregnant or breast feeding,

ask a health professional before use.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away. Package not child resistant.

Store

at 20°C - 25°C (68°F - 77°F)

Directions

Adults 18 years and children 12 years and older:

- apply product directly to affected area
- product may be used as necessary, but should not be used more than four times per day.
- wash hands immediately afterwards

Children 12 years or younger: ask a doctor

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.

For Questions or Comments

Please Email info@TerrainRX.com

Relabeled by:

Enovachem PHARMACEUTICALS

Torrance, CA 90501

Made in the U.S.A.

Patent Pending

Principal Display Panel

Relabeled By:



Enovachem
PHARMACEUTICALS

379 Van Ness Ave.
Suite 1403-1406
Torrance, CA 90501

LidoPro Topical Pain Relief Ointment

NDC: 76420-038-12

Qty: 121

Manufactured For: Terrain Pharmaceuticals

Source NDC: 53225-1022-1

Description: Active Ingredients: Menthol 10%/Capsaicin 0.0325%/Lidocaine HCl 4%/Methyl Salicylate 27.5%

Lot #: XXXXXXXX

Exp: 2/5/2020

Batch #: XXXXXXXX

Drug Status: OTC

CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION. SEE PACKAGE INSERT.
KEEP OUT OF REACH OF CHILDREN. STORE AT 20-25C (68-77F) [SEE USP CONTROLLED ROOM TEMP].



(01) 0 0376420 03812 2

(17) 200205

(10) XXXXXXXX

(21) 125133

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LIDOPRO

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76420-038(NDC:53225-1022)
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
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)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76420-038-12	121 g in 1 BOTTLE; Type 0: Not a Combination Product	02/05/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	01/01/2014	

Labeler - Asclemed USA, Inc. (059888437)

Establishment

Name	Address	ID/FEI	Business Operations
ASCLEMED USA INC. DBA ENOVACHEM		059888437	relabel(76420-038)

Revised: 10/2023

Asclemed USA, Inc.