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

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

Manufactured for
Terrain Pharmaceuticals
Reno, NV 89501

Made in the U.S.A.
Patent Pending

Principal Display Panel

NDC 53225-1022-1

Professional Use Only

LidoPro ™

Topical Pain Relief

Ointment & Applicator

Hands-Free Applicator

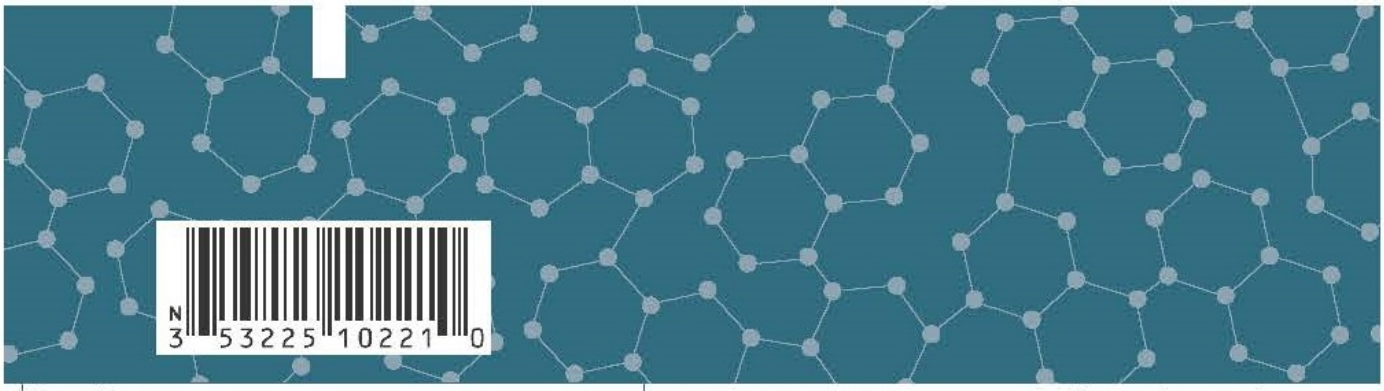
Reduced Scent

Deep Penetrating

Long Lasting

Soothing

Net WT 4 oz. (121 g)



NDC 53225-1022-1

Professional Use Only

Drug Facts

Active Ingredients	Purpose
Lidocaine HCL 4%	Topical Anesthetic
Methyl Salicylate 27.5%	Topical NSAID
Menthol 10%	Topical Analgesic
Capsaicin 0.0325%	Counterirritant

Uses: Temporarily relieves minor aches and muscle pains associated with: • arthritis • simple back pain • strains • muscle soreness

Warnings:
For external use only

Do not use
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- with bandage or a heating pad
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LidoPro®

For Questions or Comments
Please Email info@TerrainRx.com

Manufactured For:
Terrain Pharmaceuticals
Reno, NV 89501

Made in the U.S.A.

LidoPro®

Topical Pain Relief
Ointment & Applicator

Hands-Free Applicator
Reduced Scent

Deep Penetrating
Long Lasting
Soothing

NET WT 4 oz. (121 g)

LIDOPRO

capsaicin, lidocaine, menthol, and methyl salicylate ointment

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	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:53225-1022-1	121 g in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2014	
2	NDC:53225-1022-3	300 in 1 CARTON	01/01/2014	12/08/2023
2	NDC:53225-1022-2	2.5 g in 1 PACKET; Type 0: Not a Combination Product		
3	NDC:53225-1022-4	26 g in 1 TUBE; Type 0: Not a Combination Product	01/01/2014	

Marketing Information

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

Labeler - Terrain Pharmaceuticals (078358750)

Revised: 12/2023 Terrain Pharmaceuticals