LIDOPRO- capsaicin, lidocaine, menthol, and methyl salicylate ointment
Aidarex Pharmaceuticals LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

LIDOPRO OINTMENT

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.

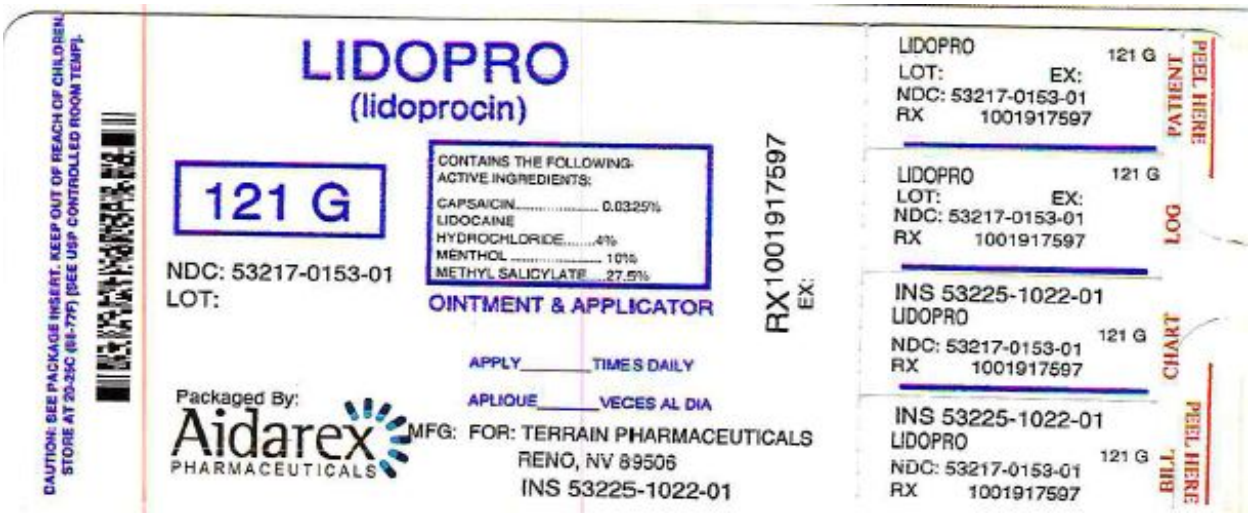
For Questions or Comments

Please Email info@TerrainRX.com

Manufactured for
Terrain Pharmaceuticals
Reno, NV 89501

Made in the U.S.A.
Patent Pending

Principal Display Panel



SPL Label

LIDOPRO

capsaicin, lidocaine, menthol, and methyl salicylate ointment

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:53217-153(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)	
POLYOXYL 100 STEARATE (UNII: YD01N1999R)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53217-153-01	121 g in 1 BOTTLE; 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 NOT FINAL	part348	01/01/2014	

Labeler - Aidarex Pharmaceuticals LLC (801503249)

Revised: 2/2017 Aidarex Pharmaceuticals LLC