AROMALIEF LIDOCAINE ROLL ON- lidocaine hcl, menthol lotion Marketites 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.

Aromalief LidoHCL

Active Ingredients

Lidocaine HCL 4% w/w

Menthol 1% w/w

Purpose

Topical analgesic

Topical analgesic

USES For temporary relief of pain.

Warnings

For external use only. Avoid contact with eyes.

Do not use in large quantities, particularly over raw surfaces, or blistered areas.

Stop use and ask a doctor if condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days.

Keep out of reach of children, if swallowed, get medical help or contact a Poison Control Center right away.

If pregnant or breast feeding, ask a health professional.

Directions adults and children 2 years of age and older: apply to affected area not more than 3 to 4 times daily.

Children under 2 years of age: consult a doctor.

Other Information

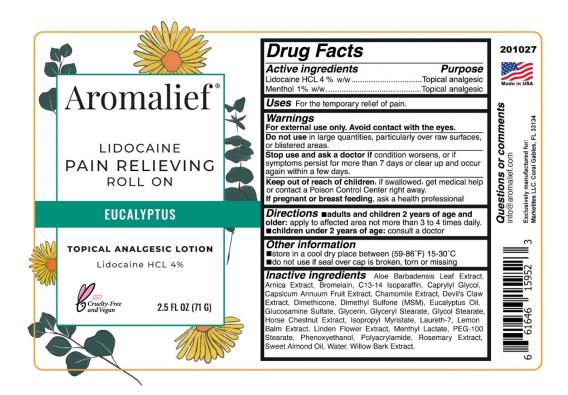
store in a cool dry place between (59-86°F) 15-30°C

don't use if seal over cap is broken, torn or missing

Inactive Ingredients

Aloe Barbadensis Leaf Extract, Arnica Extract, Bromelain, C13-14 Isoparaffin, Caprylyl Glycol, Capsicum Annuum Fruit Extract, Chamomile Extract, Devil's Claw Extract, Dimethicone, Dimethyl Sulfone (MSM), Eucalyptus Oil, Glucosamine Sulfate, Glycerin, Glyceryl Stearate, Glycol Stearate, Horse Chestnut Extract, Isopropyl Myristate, Laureth-7, Lemon Balm Extract, Linden Flower Extract, Menthyl Lactate, PEG-100 Stearate, Phenoxyethanol, Polyacrylamide, Rosemary Extract, Sweet Almond Oil, Water, Willow Bark Extract

Questions or comments



AROMALIEF LIDOCAINE ROLL ON

lidocaine hcl, menthol lotion

Product Information	Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72393-204	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	1 g in 100 g	
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	4 g in 100 g	

Inactive Ingredients		
Ingredient Name	Strength	
GLYCERIN (UNII: PDC6A3C0OX)		
GLYCOL STEARATE (UNII: 0324G66D0E)		
HORSE CHESTNUT (UNII: 3C18L6RJAZ)		
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)		
PEG-100 STEARATE (UNII: YD01N1999R)		
ARNICA MONTANA (UNII: O80TY208ZW)		
CAPRYLYL GLYCOL (UNII: 00YIU5438U)		

CHAMOMILE (UNII: FGL3685T2X)	
ROSEMARY OIL (UNII: 8LGU7VM393)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
LEMON BALM OIL (UNII: MJ76269K9S)	
LINDEN LEAF (UNII: RU6O456OJ1)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SALIX NIGRA BARK (UNII: QU52J3A5B3)	
EUCALYPTUS GLOBULUS LEAF (UNII: S546YLW6E6)	
GLUCOSAMINE SULFATE POTASSIUM CHLORIDE (UNII: 15VQ11I66N)	
GLYCERYL MONOSTEARATE (UNII: 2300U9XXE4)	
MENTHYL LACTATE, (-)- (UNII: 2BF9E65L7I)	
ALMOND OIL (UNII: 66YXD4DKO9)	
HARPAGOPHYTUM PROCUMBENS ROOT (UNII: 10YM338E89)	
FRUIT BROMELAIN (UNII: F0ZCA6O9QT)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CAPSICUM ANNUUM WHOLE (UNII: 7FKZ3QQQ1F)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
POLYACRYLAMIDE (10000 MW) (UNII: E2KR9C9V2I)	
LAURETH-7 (UNII: Z95S6G8201)	

ı	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
		NDC:72393- 204-25	71 g in 1 BOTTLE, WTH APPLICATOR; Type 0: Not a Combination Product	04/06/2022	

Marketing In	larketing Information		
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	04/06/2022	

Labeler - Marketites LLC (036140212)

Revised: 4/2022 Marketites LLC