

KOPE PAIN RELIEF GEL- lidocaine gel
CA-BOTANA INTERNATIONAL

Kope Pain relief gel

OTC - ACTIVE INGREDIENT

Lidocaine 4% Topical Analgesic

Other Safety Information

Protect this product from excessive heat and direct sun

OTC - ASK DOCTOR

Stop use and ask a doctor if redness is present. irritation develops. conditions worsens or symptoms persist more than 7 days. symptoms clear up and occur again within a few days

OTC - PURPOSE SECTION

Uses: for temporary relief of pain

Keep out of reach of children

Keep out of reach of children

INACTIVE INGREDIENTS

CAPRYLYL GLYCOL, POLYOXYL 40 CASTOR OIL, ALOE VERA LEAF, ARNICA MONTANA, BUTYLENE GLYCOL, ETHYLHEXYLGLYCERIN, HEXYLENE GLYCOL, MELISSA OFFICINALIS, MENTHA PIPERITA, MENTHOL, PEG-40 HYDROGENATED CASTOR OIL, PHENOXYETHANOL, POTASSIUM SORBATE, PPG-26-BUTETH-26, ROSMARINUS OFFICINALIS, ROYAL JELLY, TRIDECETH-9, TROLAMINE SALICYLATE, ALPHA-TOCOPHEROL ACETATE, WATER, XANTHAN GUM, 1,2 HEXANEDIOL, DI METHYL SULFUXIDE (MSM), PROPYLENE GLYCOL, EDETATE SODIUM TETRAHYDRATE, ALCOHOL, PHOSPHATYLCHOLINE.

Warnings

For external use only, Avoid contact with eyes. Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away. If conditions worsens or symptoms persist for more than 7 days or clear up and occur again within a few days, discontinue use of this product consult a doctor. Do not use in large quantities particularly over raw surfaces or blistered areas.



Dosage & Administration

Adult and children 12 years of age and older: Apply and massage 2 to 3 layers onto affected area up to 3 times a day. Children under 12 years of age: consult a doctor.

Indications & usage

Apply and massage 2 to 3 layers onto affected area up to 3 times a day

Package label principal panel

 <p>Created by Board Certified Pain Physician</p> <p>Stain Free and Odorless</p> <p><i>Contains Lidocaine, Salicylate, Arnica, MSM</i></p> <p>Net Wt. 1.7 fl oz (50 mL)</p>	<p>Drug Facts</p>				
	<table border="1"> <thead> <tr> <th>Active Ingredients</th> <th>Purpose</th> </tr> </thead> <tbody> <tr> <td>Lidocaine 4%.....</td> <td>Topical Analgesic</td> </tr> </tbody> </table>	Active Ingredients	Purpose	Lidocaine 4%.....	Topical Analgesic
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	Lidocaine 4%.....	Topical Analgesic			
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	<p>Warnings: For external use only. Avoid contact with eyes. If condition worsens or symptoms persist for more than 7 days or clear up and occur again within a few days, discontinue use of this product and consult a doctor. Do not use in large quantities, particularly over raw surfaces or blistered areas.</p>				
<p>Directions: Adult and children 12 years of age and older: Apply and massage 2 to 3 layers onto affected area up to 3 times a day. Children under 12 years of age: consult a doctor.</p>					
<p>Inactive Ingredients: 1,2 Hexanediol, Alcohol, Aloe Barbadensis (Aloe Vera) Extract, Arnica montana (Arnica) Beta Glucan, Butylene Glycol, Caprylyl Glycol, Ethylhexylglycerin, Hexylene Glycol, Melissa Officinalis, Mentha Piperita (Peppermint), Menthol, Methyl Sulfonyl Methane, PEG 40- Hydrogenated Castor Oil, Phenoxyethanol, Phosphatidylcholine, Potassium Sorbate, PPG-26 Butheth-26, Propylene Glycol, Rosmarinus officinalis (Rosemary) Leaf Extract, Royal Jelly, Tetrasodium EDTA, Trideceth-9, Trolamine Salicylate, Tocopherol (Vitamin E), Water, Xanthan Gum.</p>					
<p>Other Information: Protect this product from excessive heat and sun.</p>					
<p> Made in USA www.KopePainGel.com</p> <p>Manufactured for Leguys Corporation, Newport Beach CA, 92660 NDC:35192-026-10</p>					

KOPE PAIN RELIEF GEL

lidocaine gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:35192-026
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	4 g in 50 g

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
.ALPHA.-GLUCAN OLIGOSACCHARIDE (UNII: S95658MI3W)	
EDETATE SODIUM TETRAHYDRATE (UNII: L13NHD21X6)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
DIPALMITOYLPHOSPHATIDYLCHOLINE, DL- (UNII: 2W15RT5V7V)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ARNICA MONTANA (UNII: O80TY208ZW)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
MELISSA OFFICINALIS (UNII: YF70189L0N)	
MENTHA PIPERITA (UNII: 79M2M2UDA9)	
MENTHOL (UNII: L7T10EIP3A)	
PEG-4 HYDROGENATED CASTOR OIL (UNII: 43SW2U113W)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
PPG-26-BUTETH-26 (UNII: 2II1K6TZ4P)	
ROSMARINUS OFFICINALIS WHOLE (UNII: EA3289138M)	
ROYAL JELLY (UNII: L497I37F0C)	
TRIDECETH-9 (UNII: X9HD79I514)	
TROLAMINE SALICYLATE (UNII: H8O4040BHD)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WATER (UNII: 059QF0KO0R)	
XANTHAN GUM (UNII: TTV12P4NEE)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	

Product Characteristics

Color	yellow (Brownish-Yelow)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:35192-026-10	50 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/30/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	06/30/2017	

Labeler - CA-BOTANA INTERNATIONAL (106276728)

Establishment

Name	Address	ID/FEI	Business Operations
CA-BOTANA INTERNATIONAL		106276728	manufacture(35192-026)

Revised: 12/2024

CA-BOTANA INTERNATIONAL