

**KOPE PAIN RELIEF GEL- lidocaine gel**  
**CA-BOTANA INTERNATIONAL**

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**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><b>Stain Free and Odorless</b></p> <p><i>Contains Lidocaine, Salicylate, Arnica, MSM</i></p> <p>Net Wt. 1.7 fl oz (50 mL)</p>	<p><b>Drug Facts</b></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			
	<p><b>Uses:</b> For temporary relief of pain.</p>				
	<p><b>Warnings:</b> 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><b>Directions:</b> 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><b>Inactive Ingredients:</b> 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><b>Other Information:</b> Protect this product from excessive heat and sun.</p>					
<p> <b>Made in USA</b>    <a href="http://www.KopePainGel.com">www.KopePainGel.com</a></p> <p>Manufactured for Leguys Corporation, Newport Beach CA, 92660    NDC:35192-026-10</p>					

KOPE PAIN RELIEF GEL			
lidocaine gel			
Product Information			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:35192-026
<b>Route of Administration</b>	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: 10/2023

CA-BOTANA INTERNATIONAL