

LUBRACANE- lubracane gel
Ozeion LLC

Lubracane

Active Ingredients

Menthol 0.24% Topical Analgesic

Uses

For the temporary relief of minor aches and pains of muscles and joints associated with arthritis and minor injuries including sprains, strains and bruises.

Warnings

For external use only. Avoid contact with eyes and open wounds. Do not use if allergic to any of its ingredients.

Keep out of reach of children. If swallowed, get medical help or contact Poison Control immediately.

Do Not Use

If pregnant, breast feeding or intending to become pregnant.

Precautions

Stop use and consult a physician if pain persists beyond 3 days, a rash or irritation develops, or if condition worsens, or resolves and then returns.

Directions

Adults and Children over 12. Apply an adequate amount of gel to cover affected area. On day 1 apply 2 to 3 times within the first hour, and up to six times that day. On the following days, apply 3 to 4 times a day, as needed.

Inactive Ingredients

Filtrated deionized water, MethylSulfonylMethane (MSM), Acrylates/C-10-30, Alkyl Acrylate Crosspolymer, Polysorbate-20, Propylene Glycol (and) Dizolidinyl Urea (and) Iodopropynyl Butylcarbamate, Ammonium Hydroxide.

Other Information

Store between 68° and 74°F (20°-23°C) with closed cover. Do not apply with hot pack.

Questions or Comments

Email us at: info@lubracane.com

Label

 <p>72235 00000 2</p>	<p>Drug Facts Active Ingredients Purpose Menthol 0.24%.....Topical Analgesic</p>	<p>Drug Facts <i>Continued</i> Precautions Stop use and consult a physician if pain persists beyond 3 days, a rash or irritation develops, or if condition worsens, or resolves and then returns.</p>	<p>LUBRACANE™ LESS PAIN · MORE MOVEMENT</p>  <p>MEDICAL DOCTOR DEVELOPED 4.0 fl.oz.</p>	
	<p>Uses For the temporary relief of minor aches and pains of muscles and joints associated with arthritis and minor injuries including sprains, strains and bruises.</p>	<p>Directions Adults and Children over 12. Apply an adequate amount of gel to cover affected area. On day 1 apply 2 to 3 times within the first hour, and up to six times that day. On the following days, apply 3 to 4 times a day, as needed.</p>		<p>Drug Facts <i>Continued</i> Inactive Ingredients Filtrated deionized water, MethylSulfonylMethane (MSM), Acrylates/C-10-30 Alkyl Acrylate Crosspolymer, Polysorbate-20, Propylene Glycol (and) Diazolidinyl Urea (and) Iodopropynyl Butylcarbamate, Ammonium Hydroxide.</p>
	<p>Warnings For external use only. Avoid contact with eyes and open wounds. Do not use if allergic to any of its ingredients.</p> <p>Keep out of reach of children. If swallowed, get medical help or contact Poison Control immediately. Do not use if pregnant, breast feeding or intending to become pregnant.</p>	<p>Other Information Store between 68° and 74° F (20°-23° C) with closed cover. Do not apply with hot pack.</p> <p>Questions or Comments Email us at: info@lubracane.com</p>		



The image shows a detailed template for the Lubracane gel tube label. It includes a top flap with the Lubracane logo and tagline. The main body of the label is divided into three vertical sections:

- Left Section:** Contains the 'Drug Facts' section with 'Active Ingredients', 'Purpose', 'Uses', 'Warnings', 'Precautions', and 'Directions'.
- Middle Section:** Contains 'Drug Facts Continued' with 'Inactive Ingredients', 'Other Information', and 'Questions or Comments'. It also features the Lubracane logo and tagline.
- Right Section:** Features the 'New Pain Relief Gel' text, the Lubracane logo, tagline, and 'MEDICAL DOCTOR DEVELOPED' with '4.0 fl.oz.'.

Additional elements include a 'KO Outside' label on the right side and a barcode at the bottom of the template.

LUBRACANE

lubracane gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72235-5838
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.24 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
AMMONIA (UNII: 5138Q19F1X)	
WATER (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72235-5838-1	118.3 mL in 1 JAR; Type 0: Not a Combination Product	01/15/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M341	01/15/2018	

Labeler - Ozeion LLC (067331308)

Establishment

Name	Address	ID/FEI	Business Operations
Abbe Laboratories, Inc		781745286	manufacture(72235-5838)