LUBRACANE- lubracane gel
Ozeion 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.

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.

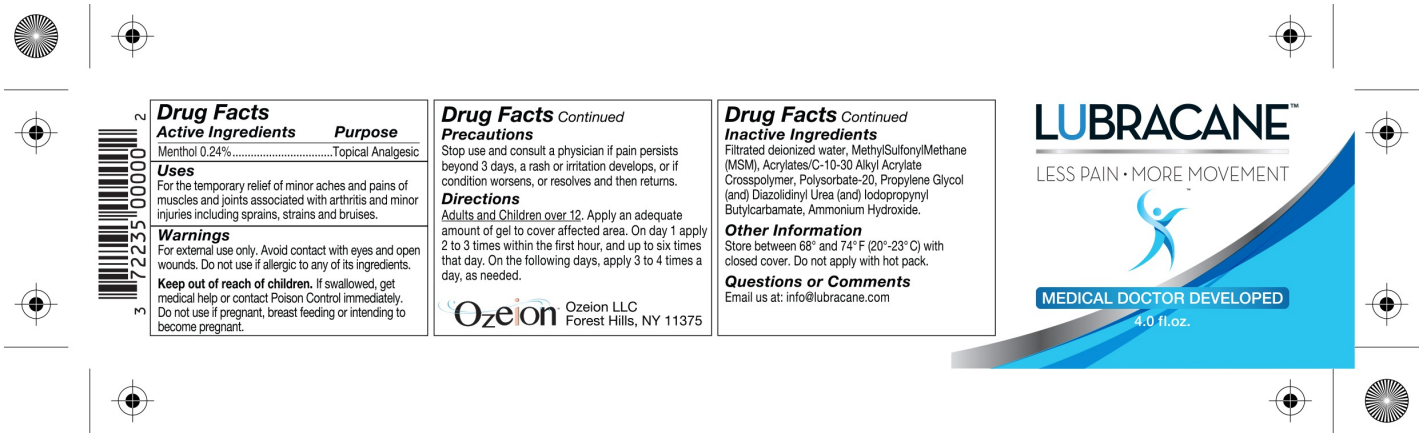
Other Information

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



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 final	part341	01/15/2018	

Labeler - Ozeion LLC (067331308)

Establishment

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

Revised: 1/2023 Ozeion LLC