NEPTUNE ICE- lidocaine, menthol, camphor, and dimethicone gel gel Neptune Products L.L.C.

Neptune Ice

<u>Methemoglobinemia</u>

Cases of methemoglobinemia have been reported in association with local anesthetic use. Although all patients are at risk for methemoglobinemia, patients with glucose-6-phosphate dehydrogenase deficiency, congenital or idiopathic methemoglobinemia, cardiac or pulmonary compromise, infants under 6 months of age, and concurrent exposure to oxidizing agents or their metabolites are more susceptible to developing clinical manifestations of the condition. If local anesthetics must be used in these patients, close monitoring for symptoms and signs of methemoglobinemia is recommended.

Signs and symptoms of methemoglobinemia may occur immediately or may be delayed some hours after exposure and are characterized by a cyanotic skin discoloration and abnormal coloration of the blood. Methemoglobin levels may continue to rise; therefore, immediate treatment is required to avert more serious central nervous system and cardiovascular adverse effects, including seizures, coma, arrhythmias, and death. Discontinue lidocaine-containing products and any other oxidizing agents. Depending on the severity of the symptoms, patients may respond to supportive care, i.e., oxygen therapy, hydration. More severe symptoms may require treatment with methylene blue, exchange transfusion, or hyperbaric oxygen

DRUG FACTS

Active Ingredient

Lidocaine 4%

Purpose

Topical Anesthetic

Active Ingredient

Menthol 1%

Purpose

Topical Analgesic

Active Ingredient

Camphor 3%

Purpose

Topical Analgesic

Active Ingredient

Dimethicone 3%

Purpose

Skin Conditioner

Uses:

For the temporary relief of joint pain and muscle pain associated with:

- Arthritis
- Backache
- Discomfort
- Cramps
- Neckache
- Soreness
- Sprains
- Strains

Warnings

For External Use Only

Flammable

Keep away from excessive heat or open flame

Do Not Use

- On damaged or irritated skin
- With a bandage or heating pad
- If you are allergic to any ingredients in this product
- Other than as directed

When Using This Product

Avoid contact with the eyes

Stop Use and Ask a Doctor If

- Condition worsens
- Excessive skin irritation develops
- Symptoms persist for more than 7 days, or symptoms clear up and occur again within 3 days

If You Are Pregnant or Breast Feeding

Ask a health professional before use

Keep Out of Reach of Children

If ingested, seek medical help or contact a Poison Control Center immediately

Directions

Adults and Children 12 years of Age and Older:

- Clean and dry the affected area
- Apply product directly to your skin, up to 4 times daily

Other Information

• Store in a cool, dry place with lid tightly closed

Inactive Ingredients

Aloe Barbadensis Leaf Juice, Arnica Montana Flower, Boswellia Serrata Extract, Carbomer, Ethylhexylglycerin, FD&C Blue #1, Methylsulfonylmethane, Phenoxyethanol, Polysorbate 20, SD-Alcohol 40B, Sorbitol, Triethanolamine, Water.

Questions or Comments?

(877) 985-8377

Principal Display Panel





Manufactured in the U.S.A. for: Neptune Products, LLC Las Vegas, NV 89107

No Animal Testing Paraben-Free NDC 72594-1846-8



Drug Facts	
Active Ingredients Lidocaine 4% Menthol 1% Camphor 3% Dimethicone 3%	Topical Analgesic
Uses For the temporary relief of joint pain and associated with: • Arthritis • Backache • Cramps • Neckache • Soreness • Sp.	muscle pain • Discomfort rains • Strains
Warnings For External Use Only	
Flammable: Keep away from excessive	heat or open flame
Do Not Use: • On damaged or irritated • With a bandage or heating pad • If you are allergic to any ingredients in • Other than as directed	skin this product
When Using This Product: Avoid con	

Stop Use and Ask a Doctor If:

Condition worsens

Excessive skin irritation develops

Symptoms persist for more than 7 days, or symptoms clear up and occur again within 3 days

If You Are Pregnant or Breast-Feeding: Ask a health professional before use

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Adults and Children 12 Years of Age and Older:
• Clean and dry the affected area
• Apply product directly to your skin, up to 4 times daily

Other Information

• Store in a cool, dry place with lid tightly closed

Inactive Ingredients: Arnica Montana Flower, Boswellia Serrata Extract, Carbomer, Ethylhexylglycerin, FD&C Blue #1, Methylsulfonylmethane, Organic Aloe Barbadensis Leaf Juice, Phenoxyethanol, Polysorbate-20, SD-Alcohol 40B, Sorbitol, Triethanolamine, Water

Questions or Comments? info@neptuneice.cool

NEPTUNE ICE

lidocaine, menthol, camphor, and dimethicone gel gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72594-1846
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
CAMPHOR (NATURAL) (UNII: N20HL7Q941) (CAMPHOR (NATURAL) - UNII:N20HL7Q941)	CAMPHOR (NATURAL)	0.0291 g in 1 mL	
DIMETHICONE (UNII: 92RU3N3Y10) (DIMETHICONE - UNII:92RU3N3Y10)	DIMETHICONE	0.0291 g in 1 mL	
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	0.0388 g in 1 mL	

Inactive Ingredients		
Ingredient Name	Strength	
ALOE VERA LEAF (UNII: ZY81Z83H0X)		
POLYSORBATE 20 (UNII: 7T1F30V5YH)		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)		
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)		
PHENOXYETHANOL (UNII: HIE492ZZ3T)		
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)		
BOSWELLIA SERRATA RESIN OIL (UNII: 5T1XCE6K8K)		
WATER (UNII: 059QF0KO0R)		
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)		
ALCOHOL (UNII: 3K9958V90M)		
TROLAMINE (UNII: 903K93S3TK)		
SORBITOL (UNII: 506T60A25R)		

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
		89 mL in 1 TUBE, WTH APPLICATOR; Type 0: Not a Combination Product	10/10/2018	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	10/10/2018	

Labeler - Neptune Products L.L.C. (081502369)

Revised: 12/2023 Neptune Products L.L.C.