NEPTUNE ICE- lidocaine, menthol, camphor, and dimethicone gel
A-S Medication Solutions

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.

Neptune Ice

Methemoglobinemia

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

HOW SUPPLIED

Product: 50090-4640

NDC: 50090-4640-0 89 mL in a TUBE, WITH APPLICATOR

Lidocaine, Menthol, Camphor, and Dimethicone Gel

NEPTUNE ICE

lidocaine, menthol, camphor, and dimethicone gel

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50090-4640(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: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	0.0291 g in 1 mL
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	0.0388 g in 1 mL
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.0097 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)	
INDIAN FRANKINCENSE OIL (UNII: 5T1XCE6K8K)	
WATER (UNII: 059QF0KO0R)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
ALCOHOL (UNII: 3K9958V90M)	
TROLAMINE (UNII: 9O3K93S3TK)	

SORBITOL (UNII: 506T60A25R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50090-4640-0	89 mL in 1 TUBE, WITH APPLICATOR; Type 0: Not a Combination Product	10/22/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	10/10/2018	

Labeler - A-S Medication Solutions (830016429)

Establishment

Name	Address	ID/FEI	Business Operations
A-S Medication Solutions		830016429	RELABEL(50090-4640)

Revised: 6/2021 A-S Medication Solutions