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

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 Patch

DRUG FACTS

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.

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
- Cramps
- Discomfort
- 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 Barbadensls Leaf Extract, Alcohol, Arnlca Montana Flower Extract, Boswellia Serrata Extracl Butylene Glycol Cellulose Gum Dihydroxyaluminum Aminoecstete, Blycerin, lsopropyl Myristate, Msttwlsulfonylmethene, Partially Neutralized Polyacrylate, Phenoxvethanol, Polvsorbate 80, Porvvinyl Pyrrolidone, Propylene Glycol, Tartaric Acid, Tetrasodium EDTA, Water.

Questions or Comments?

Info@neptuneice.cool

Principal Display Panel

NEPTUNE ICE PATCH

lidocaine, menthol, camphor, and dimethicone patch patch

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:72594-1847
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAMPHOR (NATURAL) (UNII: N20HL7Q941) (CAMPHOR (NATURAL) - UNII:N20HL7Q941)	CAMPHOR (NATURAL)	450 mg
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	450 mg
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	600 mg
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	150 mg

Inactive Ingredients

Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
DIHYDROXYALUMINUM AMINOACETATE (UNII: DO250MG0W6)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
EDETATE SODIUM (UNII: MP1J8420LU)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POVIDONE (UNII: FZ989GH94E)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
POLYACRYLIC ACID (250000 MW) (UNII: 9G2MAD7J6W)	
BOSWELLIA SERRATA RESIN OIL (UNII: 5T1XCE6K8K)	
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	
TARTARIC ACID (UNII: W4888I119H)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72594-1847-8	2 in 1 BOX	04/12/2019	04/12/2019
1		5 in 1 POUCH		
1		15000 in 1 PATCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	04/12/2019	

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

Revised: 4/2021 Neptune Products L.L.C.