

**ARCTIC HEAT- menthol, methyl salicylate cream**  
**Renu Laboratories, LLC**

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**ARCTIC HEAT**

**ACTIVE INGREDIENTS**

Menthol 2%

Methyl Salicylate 10%

**PURPOSE**

Topical Analgesic

Topical Analgesic

**USES**

Temporarily relieves minor aches and pains of muscle and joints due to: arthritis, simple backache, sprains, strains and bruises

**Warnings**

For external use only

**When using this product**

- Do not apply to wounds or damaged skin
- Do not bandage tightly
- Do not use in or near eyes; if product gets into eyes rinse thoroughly with water
- Do not use with an electric heating pad

**Stop use and ask doctor if**

- Conditions worsen
- Symptoms last for more than 7 days or clear up and occur again within a few days
- A rash or irritation develops

**If pregnant or breast-feeding,**

Ask a health professional before use.

**Keep out of reach of children.**

If swallowed, get medical help or contact a Poison Control Center right away.

**Inactive Ingredients**

Allantoin, Benzoic Acid, C13-14 Isoparaffin, Capsicum Frutescens Fruit Extract, Cetearyl Alcohol, Cetearyl Glucoside, Dehydroacetic Acid, Deionized Water, Emu Oil, Eucalyptus Globulus Leaf Oil, Glyceryl Stearate, Laureth-7, Mentha Piperita (Peppermint) Oil, Niacinamide, PEG-100 Stearate, Phenoxyethanol, Stearic Acid.

**ARCTIC HEAT**

***Dual Active Botanical Warming Formula with Emu Oil***

Manufactured by:

Renu Labs Inc.

Ivyland, PA 18974

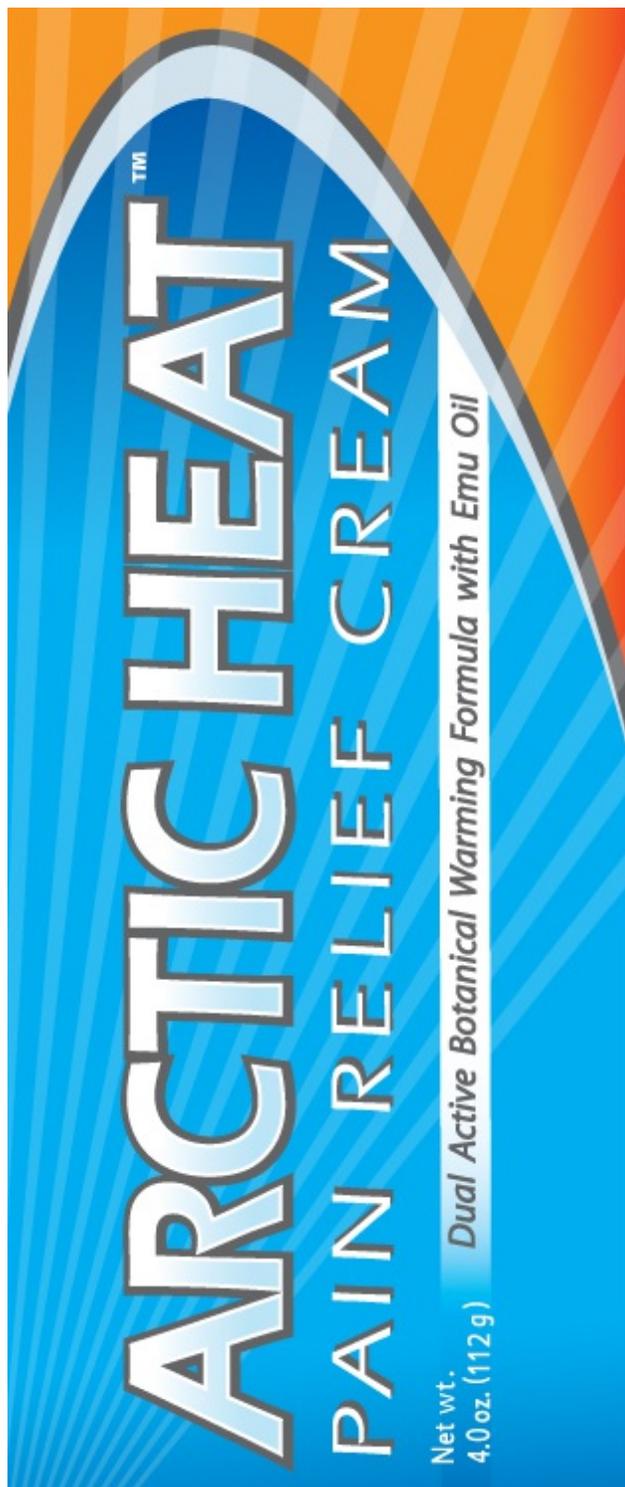
[www.RenuLabs.com](http://www.RenuLabs.com)

**Directions**

**Adults and children 12 years of age and**

**older:** Apply directly to affected area no more than 3 to 4 times daily.

**ARCTIC HEAT TUBE**



<b>Drug Facts</b>	
<b>Active ingredients</b>	<b>Purpose</b>
Menthol 2%.....	Topical Analgesic
Methyl Salicylate 10% .....	Topical Analgesic
<b>Uses</b>	
Temporarily relieves minor aches and pains of muscle and joints due to: arthritis, simple backache, sprains, strains and bruises	
<b>Warnings</b>	
For external use only	
<b>When using this product</b>	
<ul style="list-style-type: none"> <li>• Do not apply to wounds or damaged skin</li> <li>• Do not bandage tightly</li> <li>• Do not use in or near eyes: if product gets into eyes rinse thoroughly with water</li> <li>• Do not use with electric heating pad</li> </ul>	
<b>Stop use and ask doctor if</b>	
<ul style="list-style-type: none"> <li>• Conditions worsen</li> <li>• Symptoms last for more than 7 days or clear up and occur again within a few days</li> <li>• A rash or irritation develops</li> </ul>	
<b>If pregnant or breast-feeding</b> , Ask a health professional before use.	
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b>	
<b>Adults and children 12 years of age and older:</b> Apply directly to affected area no more than 3 or 4 times daily	
<b>Children under 12 years of age:</b> Ask a doctor	
<b>Inactive ingredients</b>	
Allantoin, Benzoic Acid, C13-14 Isoparaffin, Capsicum Frutescens Fruit Extract, Cetearyl Alcohol, Cetearyl Glucoside, Dehydroacetic Acid, Deionized Water, Emu Oil, Eucalyptus Globulus Leaf Oil, Glyceryl Stearate, Laureth-7, Mentha Piperita (Peppermint) Oil, Niacinamide, PEG-100 Stearate, Phenoxyethanol, Stearic Acid.	
<b>Manufactured by:</b> <b>Renu Labs Inc.</b> Ivyland, PA 18974 <a href="http://www.RenuLabs.com">www.RenuLabs.com</a>	

## ARCTIC HEAT

menthol, methyl salicylate cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:76348-414
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>METHYL SALICYLATE</b> (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	11.2 g in 112 g
<b>MENTHOL</b> (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	2.24 g in 112 g

### Inactive Ingredients

Ingredient Name	Strength
<b>NIACINAMIDE</b> (UNII: 25X51I8RD4)	
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	
<b>CETEARYL GLUCOSIDE</b> (UNII: 09FUA47KNA)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>PEPPERMINT OIL</b> (UNII: AV092KU4JH)	
<b>C13-14 ISOPARAFFIN</b> (UNII: E4F12ROE70)	
<b>DEHYDROACETIC ACID</b> (UNII: 2KAG279R6R)	
<b>PEG-100 STEARATE</b> (UNII: YD01N1999R)	
<b>TABASCO PEPPER</b> (UNII: J1M3NA843L)	
<b>ALLANTOIN</b> (UNII: 344S277G0Z)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>BENZOIC ACID</b> (UNII: 8SKN0B0MIM)	
<b>LAURETH-7</b> (UNII: Z95S6G8201)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>SODIUM ACRYLOYLDIMETHYLTAURATE-ACRYLAMIDE COPOLYMER (1:1; 90000-150000 MPA.S)</b> (UNII: 5F4963KLHS)	
<b>EMU OIL</b> (UNII: 344821WD61)	
<b>EUCALYPTUS OIL</b> (UNII: 2R04ONI662)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76348-414-01	112 g in 1 TUBE; Type 0: Not a Combination Product	09/17/2015	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	09/17/2015	

**Labeler** - Renu Laboratories, LLC (119451815)

### Establishment

Name	Address	ID/FEI	Business Operations
Renu Laboratories, LLC		119451815	manufacture(76348-414)

