

## **AROMALIEF SOOTHING PAIN RELIEF CREAM SPEARMINT- menthol lotion** **Marketites 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.*

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### **Aromalief Spearmint**

#### **Active Ingredients**

Menthol 1.0% w/w

Topical Analgesic

**Use For** temporary relief of pain

#### **Warnings**

##### **Warnings**

For external use only. Avoid contact with eyes.

**Stop use and ask a doctor** if condition worsens, symptoms persist for more than 7 days, or new symptoms occur.

**Keep out of reach of children**, if swallowed, get medical help or contact a Poison Control Center right away. **If pregnant or breastfeeding**, ask a health professional.

#### **Directions**

**Adults and children 2 years of age and older:** Apply to affected area not more than 3 to 4 times daily. **Children under 2 years of age:** consult a doctor.

#### **Other Information**

Store in a cool dry place between 68° and 77°F and relative humidity not exceeding 65%.

Do not use if seal is broken, torn or missing.

#### **Inactive Ingredients**

Aloe Barbadensis Leaf Extract, Water, Stearyl Alcohol, Prunus Amygdalus Dulcis (Sweet Almond) Oil, Isopropyl Myristate, Glyceryl Stearate, Menthyl Lactate, Glycerin, PEG 100 Stearate, Cannabis Sativa Seed Oil, Ulva lactuca Linnaeus, Fucaceae Fucus Vesiculosus, Sodium Hyaluronate, Spearmint (Mentha Viridis), Maltodextrin, Glucosamine Sulfate, Dimethyl Sulfone (MSM), L-Arginine, Glycol Stearate, Phenoxyethanol, Caprylyl Glycol

#### **Questions**

Distributed by Marketites LLC

Coral Gables, FL 33134

Made in the USA

Questions? [info@aromalief.com](mailto:info@aromalief.com)



## Drug Facts

Active Ingredient	Purpose
Menthol 1.0 % w/w .....	Topical Analgesic

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**Directions**  
■ **Adults and children 2 years of age and older:** Apply to affected area not more than 3 to 4 times daily.  
■ **Children under 2 years of age:** Consult a doctor.

**Other Information**  
■ Store in a cool dry place between 59° and 86°F  
■ Do not use if seal is broken, torn or missing.

**Inactive Ingredients**  
Aloe Barbadosis Leaf Extract, Water, Stearyl Alcohol, Prunus Amygdalus Dulcis (Sweet Almond) Oil, Isopropyl Myristate, Glyceryl Stearate, Menthyl Lactate, Glycerin, PEG 100 Stearate, Cannabis Sativa Seed Oil, Spearmint (Mentha Viridis) Leaf Oil, Ulva lactuca Linnaeus, Fucaceae Fucus Vesiculosus, Sodium Hyaluronate, Maltodextrin, Glucosamine Sulfate, Dimethyl Sulfone (MSM), L-Arginine, Glycol Stearate, Phenoxyethanol, Caprylyl Glycol

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## AROMALIEF SOOTHING PAIN RELIEF CREAM SPEARMINT

menthol lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:72393-306
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>MENTHOL</b> (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	1 g in 100 g

## Inactive Ingredients

Ingredient Name	Strength
<b>GLYCOL STEARATE</b> (UNII: 0324G66D0E)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>HYALURONATE SODIUM</b> (UNII: YSE9PPT4TH)	
<b>MALTODEXTRIN</b> (UNII: 7CVR7L4A2D)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SPEARMINT OIL</b> (UNII: C3M81465G5)	
<b>ULVA LACTUCA</b> (UNII: PHR3P25W6Y)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>ALMOND OIL</b> (UNII: 66YXD4DKO9)	
<b>ISOPROPYL MYRISTATE</b> (UNII: ORE8K4LNJS)	
<b>GLYCERYL STEARATE SE</b> (UNII: FCZ5MH785I)	
<b>PEG-100 STEARATE</b> (UNII: YD01N1999R)	
<b>CANNABIS SATIVA SEED OIL</b> (UNII: 69VJ1LPN1S)	
<b>FUCUS VESICULOSUS</b> (UNII: 535G2ABX9M)	
<b>GLUCOSAMINE SULFATE</b> (UNII: 1FW7WLR731)	
<b>MENTHYL LACTATE, (-)-</b> (UNII: 2BF9E65L7I)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>DIMETHYL SULFONE</b> (UNII: 9H4PO4Z4FT)	
<b>STEARYL ALCOHOL</b> (UNII: 2KR89I4H1Y)	
<b>ARGININE</b> (UNII: 94ZLA3W45F)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72393-306-04	0.14 g in 1 TUBE; Type 0: Not a Combination Product	03/01/2021	
2	NDC:72393-306-02	0.07 g in 1 TUBE; Type 0: Not a Combination Product	03/01/2021	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	03/01/2021	

**Labeler** - Marketites LLC (036140212)