

**NEUROFREEZE- menthol liquid**  
**Blue Heron Pharmaceuticals, LLC**

*Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.*

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**NeuroFreeze**

**Active Ingredients:**

Menthol 6%

**Purposes:**

Topical Analgesic

**Uses:**

Temporary relief of minor aches and pains of muscles and joints associated with:

- Strains
- Bruises
- Sprains

**Directions:**

**Adults and children 2 years of age and older:**

Apply to affected area not more than 3 to 4 times daily.

Rub thoroughly until gel is absorbed.

For children under 2 years of age: Ask a doctor.

**Warnings:**

**For external use ONLY.**

Do not use on wounds or damaged skin or with a heat source. **If pregnant or breastfeeding, ask a healthcare professional before use.**

**When using this product:**

- Avoid bandaging tightly
- Avoid contact with eyes
- Keep out of the reach of children

**Stop use and ask doctor if:**

- Condition worsens
- Symptoms persist for more than 7 days

**Keep out of reach of children**

If put in mouth, get medical help or contact a poison control center right away. Dispose of used product away from children and pets.

**Storage:**

- Store at 68-77°F (20-25°C) - Room Temperature
- Do not exceed 100 oF (38 °C)

**Inactive Ingredients:**

Aloe Barbadensis Leaf Juice, Camellia Sinensis (Green Tea) Leaf Extract, Caprylyl Glycol, Carbomer, Citrus Grandis (Grapefruit) Seed Extract, Citrus Limon (Lemon) Peel Oil, Decyl Glucoside, Filipendula Ulmaria (Queen of the Prairie) Flower Extract, Glycerin, Hamamelis Virginiana (Witch Hazel) Leaf Extract, Phenoxyethanol, Purified Water, Rosa Damascena Flower Water, Sodium Carbonate, Yucca Schidigera Stem Extract.

**Manufactured for:**

Blue Heron Pharmaceuticals, LLC  
2831 Allegra Way, Suite 218  
Lutz, FL 33559

Questions or concerns call 813-380-0271

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

**Packaging:**



Net Wt. 3 oz. 85.05 g

**ROLL-ON**

**Drug Facts**

**NDC 85622-0511-85**

**Active ingredient**

Menthol, USP 6.0%

**Purpose**

External analgesic

**Use**

Temporarily relieves minor aches and pains of muscles and joints associated with:  
 ■ strains ■ bruises ■ sprains.

**Warnings:**

For external use only. Do not use on wounds or damaged skin or with a heat source.  
 If pregnant or breastfeeding, ask a healthcare professional before use.

When using this product: avoid bandaging tightly ■ avoid contact with eyes  
 ■ Keep out of reach of children

Stop use and ask doctor if: ■ condition worsens ■ symptoms persist for more than 7 days ■ symptoms clear up and occur again within a few days.

**Directions:**

Adults and children 2 years of age and older: ■ apply to affected area not more than 3 to 4 times daily. ■ rub in thoroughly until gel is absorbed. ■ Children under 2 years of age: consult a doctor.

**Inactive Ingredients:**

Aloe Barbadensis Leaf Juice, Camellia Sinensis (Green Tea) Leaf Extract, Caprylyl Glycol, Carbomer, Citrus Grandis (Grapefruit) Seed Extract, Citrus Limon (Lemon) Peel Oil, Decyl Glucoside, Filipendula Ulmaria (Queen of the Prairie) Flower Extract, Glycerin, Hamamelis Virginiana (Witch Hazel) Leaf Extract, Phenoxyethanol, Purified Water, Rosa Damascena Flower Water, Sodium Carbonate, Yucca Schidigera Stem Extract.

**Questions or Comments? 813-380-0271**

**Made in the USA**



**85622-0511-85**

Manufactured for.  
 Blue Heron Pharmaceuticals  
 2831 Allegra Way Suite 218 Lutz FL 33559  
 Questions? Call: 813-380-0271  
 www.blueheronpharma.com

# NEUROFREEZE

menthol liquid

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:85622-511
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>MENTHOL</b> (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	6 g in 85 g

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>ALOE BARBADENSIS LEAF JUICE</b> (UNII: RUE8E6T4NB)	
<b>CAMELLIA SINENSIS LEAF</b> (UNII: W2ZU1RY8B0)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>CARBOMER</b> (UNII: 0A5MM307FC)	
<b>CITRUS AURANTIUM DULCIS (ORANGE) PEEL OIL</b> (UNII: AKN3KSD11B)	
<b>CITRUS LIMON (LEMON) PEEL OIL</b> (UNII: I9GRO824LL)	
<b>DECYL GLUCOSIDE</b> (UNII: Z17H97EA6Y)	
<b>FILIPENDULA ULMARIA FLOWER</b> (UNII: 06L18L32G6)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>HAMAMELIS VIRGINIANA LEAF</b> (UNII: T07U1161SV)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>ROSA DAMASCENA FLOWER</b> (UNII: JWB78P295A)	
<b>SODIUM CARBONATE</b> (UNII: 45P3261C7T)	
<b>YUCCA SCHIDIGERA STEM</b> (UNII: N59C6T6D72)	

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:85622-511-85	85 g in 1 BOTTLE, WTH APPLICATOR; Type 0: Not a Combination Product	02/23/2026	

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
unapproved drug other		02/23/2026	

**Labeler** - Blue Heron Pharmaceuticals, LLC (137019051)

## Establishment

Name	Address	ID/FEI	Business Operations
SOMBRA COSMETICS INC.		097464309	manufacture(85622-511) , label(85622-511)

Revised: 2/2026

Blue Heron Pharmaceuticals, LLC