

# **COOL AND HEAT SORE MUSCLE ROLLER EVORA LABS- menthol liquid**

## **Evora Worldwide**

*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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### **Drug Facts**

#### **Active ingredient**

#### **Purpose**

Menthol 16% ..... Topical analgesic

### **Uses**

temporarily relieves minor pain associated with:

- arthritis • simple backache • muscle strains • sprains • bruises • cramps

### **Warnings**

**For externa use only.**

**When using this product** • use only as directed • do not bandage tightly or use with a heating pad • avoid contact with eyes and mucous membranes • do not apply to wounds or damaged, broken or irritated skin • a transient burning sensation may occur upon application but generally disappears in several days • if severe burning sensation occurs, discontinue use immediately • do not expose the area treated with product to heat or direct sunlight

**Stop use and ask doctor if** • condition worsens • redness is present • irritation develops • symptoms persist for more than 7 days or clear up and occur again within a few days

**Flammable** • keep away from fire or flame

**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.

### **Directions**

adults and children over 12 years: • apply generously to

affected area • massage into painful area until thoroughly absorbed into skin • repeat as necessary, but no more than 3 to 4 times daily • IF MEDICINE COMES IN CONTACT WITH HANDS, WASH WITH SOAP AND WATER

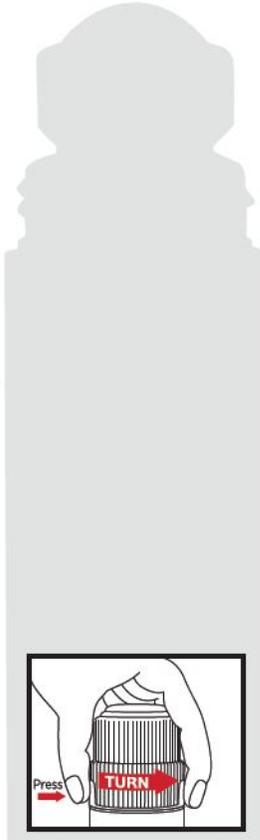
**Children 12 years or younger:** ask a doctor

**Inactive ingredients**

Acrylates/C10-30 Alkyl Acrylate  
 Crosspolymer, Capsaicin, Glycerin, Isopropyl Myristate, Propylene Glycol, SD Alcohol 40 (30%), Triethanolamine, Water

**Questions?**

1-888-793-8450

<p><b>Drug Facts</b></p> <table border="1"> <tr> <td><b>Active ingredient</b></td> <td><b>Purpose</b></td> </tr> <tr> <td>Menthol 16%</td> <td>Topical analgesic</td> </tr> </table> <p><b>Uses</b> For the temporary relief of minor aches and pains of muscles and joints associated with simple backache, arthritis, strains, bruises, and sprains.</p> <p><b>Warnings</b>  <b>For external use only.</b>  <b>Flammable</b> • keep away from fire or flame.  <b>When using this product</b> • use only as directed • do not bandage tightly or use with a heating pad • avoid contact with eyes and mucous membranes • do not apply to wounds or damaged, broken or irritated skin • a transient burning sensation may occur upon application but generally disappears in several days • if severe burning sensation occurs, discontinue use immediately • do not expose the area treated with product to heat or direct sunlight.  <b>Stop use and ask doctor if</b> • condition worsens • symptoms persist for more than 7 days or clear up and occur again within a few days.  <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.</p> <p><b>Directions</b>    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 physician.</p> <p><b>Inactive ingredients</b> Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Capsaicin, Glycerin, Isopropyl Myristate, Propylene Glycol, SD Alcohol 40 (30%), Triethanolamine, Water.</p> <p><b>Questions?</b> 1-888-793-8450</p> <p><small>*This product is not manufactured or distributed by the owner or the registered trademark ICY Hot®</small></p> <p><small>Distributed By:  <b>EVORA</b>    WORLDWIDE®    St. Petersburg, FL 33710    888-793-8450   info@evoraworld.com</small></p>	<b>Active ingredient</b>	<b>Purpose</b>	Menthol 16%	Topical analgesic	<p>EVORA LABS</p> <p><b>Cool &amp; Heat</b></p> <p>SORE MUSCLE ROLLER</p> <p><b>MENTHOL 16%</b></p> <p>TOPICAL ANALGESIC</p> <ul style="list-style-type: none"> <li>• Pain Relief Therapy for Arthritis, Backache, Muscle Strains and Sprains</li> <li>• Non-Greasy</li> <li>• Quick Drying</li> </ul> <p>2.5 fl oz (74 mL)</p>	<p>EVORA LABS</p> <p><b>Cool &amp; Heat</b></p> <p>SORE MUSCLE ROLLER</p> <p><b>MENTHOL 16%</b></p> <p>TOPICAL ANALGESIC</p> <ul style="list-style-type: none"> <li>• Pain Relief Therapy for Arthritis, Backache, Muscle Strains and Sprains</li> <li>• Non-Greasy</li> <li>• Quick Drying</li> </ul> <p>2.5 fl oz (74 mL)</p>	 <p>Package Contains One Bottle</p>
<b>Active ingredient</b>	<b>Purpose</b>						
Menthol 16%	Topical analgesic						

<b>COOL AND HEAT SORE MUSCLE ROLLER EVORA LABS</b>			
menthol liquid			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:77375-008

Route of Administration TOPICAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	16 g in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
CAPSAICIN (UNII: S07O44R1ZM)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ALCOHOL (UNII: 3K9958V90M)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77375-008-02	1 in 1 CARTON	12/21/2020	
1		74 mL in 1 BOTTLE, PLASTIC; 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	12/21/2020	

**Labeler** - Evora Worldwide (081336028)

### Establishment

Name	Address	ID/FEI	Business Operations
Inspec Solutions LLC		081030372	manufacture(77375-008)

Revised: 1/2022

Evora Worldwide