

## **THERAPEUTIC MENTHOL- menthol 2.00% gel**

### **Product Quest Mfg**

*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**

Menthol 2%.....

#### **Purpose**

External Analgesic

### **Uses**

For the temporary relief of minor aches and pains of muscles and joints associated with simple backache, arthritis, strains, bruises and sprains

### **Warnings**

#### **For external use only**

#### **When using this product • avoid**

contact with eyes • do not bandage tightly • do not apply to wounds or damaged skin • do not use with a heating pad

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

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away

### **Directions**

- for adults & children 2 years of age and older
- cleanse and dry skin
- apply to affected area not more than 3 to 4 times daily
- children under 2 years of age, consult a doctor

### **Inactive ingredients**

Ammonium Hydroxide,  
Carbomer, Cupric Sulfate, FD&C Blue No. 1, Isopropyl Alcohol, Magnesium Sulfate, Purified Water, Sodium Hydroxide, Thymol.

**Questions? 866-483-2846**



**Therapeutic Menthol Gel**  
Topical Analgesic

**Pain Reliever** Greaseless

NET WT. 8 OZ. (227 g)



<b>Drug Facts</b>	<b>Purpose</b> External Analgesic
<b>Active ingredient</b> Menthol 2%	
<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	
<b>Warnings</b> For external use only	
<b>Directions</b> For adults & children 2 years of age and older • cleanse and dry skin • apply to affected area not more than 3 to 4 times daily • children under 2 years of age, consult a doctor	
<b>Other information</b> • store at room temperature	
<b>Inactive ingredients</b> Ammonium Hydroxide, Carbomer, Cupric Sulfate, FD&C Blue No. 1, Isopropyl Alcohol, Magnesium Sulfate, Purified Water, Sodium Hydroxide, Thymol.	
<b>Questions?</b> 866-483-2846	

**Compare to the active ingredient in Mineral Ice®\***

An external pain relieving therapeutic gel for temporary relief of minor aches and pains associated with muscle strains and sprains, bruises, backache and arthritis.

\* This product is not manufactured by Novartis Consumer Health, Inc., owner of the registered trademark Mineral Ice®.

Manufactured by:  
**Product Quest Mfg, LLC.**  
330 Carswell Ave., Daytona Beach, FL 32117  
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## THERAPEUTIC MENTHOL

menthol 2.00% gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:64048-5117
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Menthol (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	Menthol	2 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
AMMONIA (UNII: 5138Q19F1X)	
CARBOMER HOMO POLYMER TYPE B (ALLYL SUCROSE CROSSLINKED) (UNII: Z135WT9208)	
Cupric Sulfate (UNII: LRX7AJ16DT)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
Isopropyl Alcohol (UNII: ND2M416302)	
MAGNESIUM SULFATE, UNSPECIFIED FORM (UNII: DE08037SAB)	
WATER (UNII: 059QF0K00R)	
Sodium Hydroxide (UNII: 55X04QC32I)	
Thymol (UNII: 3J50XA376E)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64048-5117-7	227 g in 1 JAR; Type 0: Not a Combination Product	03/24/2017	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	03/24/2017	

**Labeler** - Product Quest Mfg (927768135)

**Registrant** - Product Quest Mfg (927768135)

**Establishment**

Name	Address	ID/FEI	Business Operations
Product Quest Mfg		927768135	manufacture(64048-5117) , label(64048-5117)

Revised: 8/2018

Product Quest Mfg