

## **PREMIERES PAIN- menthol spray**

**Premiere Enterprises**

*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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## **PREMIERE'S PAIN SPRAY ROLL-ON**

**Premiere Enterprises, Inc.**

**Pain Spray**

***Drug Facts***

### **Active Ingredients**

USP Menthol 7%

### **Purpose**

Topical Analgesic

### **Uses:**

Temporary relief of minor aches and pains of muscles and joints.

### **Warnings:**

- **For external use only**
- **Flammable.** Keep away from flame.
- **Keep out of reach of children-** if swallowed get medical help or contact a poison center right away.
- Avoid contact with eyes
- Do not apply to open wounds or damaged skin
- Do not bandage tightly
- Consult a doctor if excessive skin irritation occurs, or if you are prone to allergic reactions to salicylates, including aspirin. If condition worsens, if symptoms persist for more than 7 days or clear up and recur again within a few days, discontinue use of this product and consult a doctor.

### **Directions:**

For adults and children 2 years of age and older: Shake well and apply to affected area not more than 3-4 times daily. Get extra relief by using after warm shower or bath. Will not stain clothing. For children under 2 years of age, consult a Doctor.

### **Other Information:**

Store at room temperature.

### **Inactive Ingredients:**

Water, Isopropyl Alcohol, Glycerol, Eucalyptus Leaf Oil, Wintergreen Leaf Oil, Peppermint Oil, Coconut Oil, Xanthan Gum

**1-800-576-7616 Amazing-Solutions.com**

Manufactured for:

**PREMIERE ENTERPRISES, INC.**

Los Angeles, CA 90034

**Principal Display Panel - Bottle Label**

NDC# 32472-102-03

***PREMIERE'S  
PAIN SPRAY  
ROLL ON™***

***A Miracle in Every Bottle;***

***Temporary Relief  
Of Minor Aches  
& Pains***

**MINOR SPORTS INJURIES**

**BACKACHES SORE MUSCLES**

**SPRAINS ARTHRITIS**

**MUSCLE CRAMPS**

**Net 3 fluid oz./88ml.**

**Natural Menthol • Herbal Formula**

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NEW  
LOOK  
SAME  
FORMULA

**MINOR SPORTS INJURIES**  
**BACKACHES      SORE MUSCLES**  
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Natural Menthol • Herbal Formula

## PREMIERES PAIN

menthol spray

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:32472-102
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
menthol (UNII: L7T10EIP3A) (menthol - UNII:L7T10EIP3A)	menthol	7 g in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0KO0R)	
isopropyl alcohol (UNII: ND2M416302)	
glycerin (UNII: PDC6A3C0OX)	
eucalyptus oil (UNII: 2R04ONI662)	
methyl salicylate (UNII: LAV5U5022Y)	
peppermint oil (UNII: AV092KU4JH)	

coconut oil (UNII: Q9L0O73W7L)

xanthan gum (UNII: TTV12P4NEE)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:32472-102-03	88 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/12/2011	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	01/12/2011	

**Labeler** - Premiere Enterprises (556225498)

**Registrant** - Safetec of America, Inc. (874965262)

### Establishment

Name	Address	ID/FEI	Business Operations
Safetec of America, Inc.		874965262	MANUFACTURE(32472-102)

Revised: 1/2011

Premiere Enterprises