

PREMIERES PAIN- menthol spray
Premiere Enterprises

Analgesic

PREMIERE'S PAIN SPRAY
Premiere Enterprises, Inc.

Pain Spray

Drug Facts

Active Ingredients

USP Menthol 7%

Purpose

Topical Analgesic

Uses:

Temporary relief of minor aches & 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.

Manufactured for: **PREMIERE ENTERPRISES**, Los Angeles, CA 90034
800-576-7616/ www.Amazing-Solutions.com

Principal Display Panel - Bottle Label

NDC# 32472-102-01

**PREMIER'S
PAIN SPRAY™**

A Miracle in Every Bottle!

**Temporary Relief
of Minor Aches
& Pains**

- **ARTHRITIS • SORE MUSCLES**
- **BACKACHE • SPRAINS**
- **STIFF JOINTS • MUSCLE CRAMPS**

Net 1 fluid oz./29.5 ml.

NATURAL MENTHOL • HERBAL FORMULA

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PREMIERES PAIN

menthol spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:32472-102
Route of Administration	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)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:32472-102-01	29.5 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/07/2011	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	03/07/2011	

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)

