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.

PREMIERE'S PAIN SPRAY

Premiere Enterprises, Inc.

Pain Spray

Drug Facts

Active Ingredients

USP Menthol 7%

Purpose

Topical Analgesic

Uses:

For the 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.

Questions or Comments?

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

Manufactured for:
PREMIERE ENTERPRISES, INC.
Los Angeles, CA 90034

PRINCIPAL DISPLAY PANEL

NDC# 32472-102-04

PREMIERE'S

Pain Spray™

A Miracle in Every Bottle!

Temporary Relief
of Minor Aches
& Pains

NEW LOOK
SAME FORMULA

ARTHRITIS
BACKACHE
STIFF JOINTS
SORE MUSCLES
SPRAINS
MUSCLE CRAMPS

Net 4 fluid oz./118 ml.

NATURAL MENTHOL • HERBAL FORMULA

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	.07 g in 1 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:32472-102-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/28/2010	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	12/28/2010	

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: 6/2015 Premiere Enterprises