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

$\textbf{Pain Spray}^{\text{TM}}$

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

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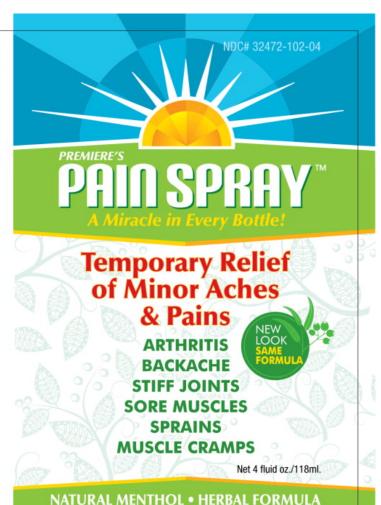
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Manufactured for: Premiere Enterprises, Inc. Amazing-Solutions Los Angeles, CA 90034





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 | | | | | |
|-----------|---|------------------|---|-----------------------------|--------------------|
| l | # | 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