ANALGESIC- menthol spray Safetec of America, Inc.

61010-8200, PAIN SPRAY

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. 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.

PRINCIPAL DISPLAY PANEL

NDC 61010-8200-1

Safetec

First Aid

Pain Spray

For Temporary

Pain Relief of

Minor Aches

And Pains

4 fl. oz. (118 ml)



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Manufactured by SAFETEC OF AMERICA, Inc. Buffalo, NY 14215 800-456-7077 www.safetec.com

ANALGESIC

menthol spray

| Product Information | | | |
|-------------------------|----------------|--------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:61010-8200 |
| Route of Administration | TOPICAL | | |

| Active Ingredient/Active Moiety | | | | |
|---|------------------------------|------------------|--|--|
| Ingredient Name | Basis of Strength | Strength | | |
| MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A) | MENTHOL, UNSPECIFIED FORM | 70 mg 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:61010- 8200-1 | 118 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product | 10/26/2011 | |

| Marketing Information | | | | |
|-----------------------|---|-------------------------|-----------------------|--|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| OTC Monograph Drug | M017 | 10/26/2011 | | |
| | | | | |

Labeler - Safetec of America, Inc. (874965262)

| Establishment | | | | |
|--------------------------|---------|-----------|----------------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| Safetec of America, Inc. | | 874965262 | manufacture(61010-8200) | |

Revised: 3/2024 Safetec of America, Inc.