

**POINT RELIEF COLD SPOT PAIN RELIEVING- menthol gel  
FABRICATION ENTERPRISES**

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**POINT RELIEF COLD SPOT Pain Relieving Gel**

**Drug Facts**

**Active Ingredients:**

Menthol USP 12%

**Purpose**

Topical Analgesic

**Uses:**

For temporary relief of minor aches and pains of muscles and joints, associated with simple backache, arthritis, bruises, strains, and/ or sprains.

**Warnings:**

- For external use only
- Avoid contact with the eyes.
- Do not apply to open wounds or damaged skin
- If symptoms persist for more than seven days, discontinue use and consult physician

**Keep out of reach of children.**

- If swallowed, consult physician
- Do not bandage tightly.

**Directions:**

Apply directly to affected area. Do not use more than four times per day.

**Ingredients:**

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aqua(Deionized Water), Arnica Montana Flower Extract, Boswellia Serrata Extract, Bromelain, Citric Acid, Diazolidinyl Urea, Eucalyptus Globulus Oil, Glycerin, Glycyrrhiza Glabra (Licorice) Root Extract, Ilex Paraguariensis (Yerba Mate) Leaf Extract, Mentha Piperita (Peppermint) Oil, Methyl Paraben, Methyl Salicylate, Methylsulfonylmethane (MSM), Polysorbate-80, Propyl Paraben, Propylene Glycol, SD-Alcohol 40B, Triethanolamine.

**Package Labeling: 475ml**

**Package Labeling: 3.8L**

**POINT RELIEF COLD SPOT PAIN RELIEVING**

menthol gel

| Product Information                                    |  |   |                      |                    |
|--|--|---|----------------------|--------------------|
| Product Type   | HUMAN OTC DRUG                           | Item Code (Source)                                  | NDC:51452-450        |                    |
| Route of Administration                                | TOPICAL                                  |   |                      |                    |
| Active Ingredient/Active Moiety                        |  |   |                      |                    |
| Ingredient Name  | Basis of Strength                        | Strength  |                      |                    |
| MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) | MENTHOL                                  | 120 mg in 1 mL                                      |                      |                    |
| Inactive Ingredients                                   |  |   |                      |                    |
| Ingredient Name  | Strength                                 |   |                      |                    |
| WATER (UNII: 059QF0K00R)                               |  |   |                      |                    |
| ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)               |  |   |                      |                    |
| INDIAN FRANKINCENSE (UNII: 4PW41QCO2M)                 |  |   |                      |                    |
| BROMELAINS (UNII: U182GP2CF3)                          |  |   |                      |                    |
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)             |  |   |                      |                    |
| DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)                   |  |   |                      |                    |
| EUCALYPTUS OIL (UNII: 2R04ONI662)                      |  |   |                      |                    |
| GLYCERIN (UNII: PDC6A3C0OX)                            |  |   |                      |                    |
| GLICYRRHIZA GLABRA (UNII: 2788Z9758H)                  |  |   |                      |                    |
| ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)            |  |   |                      |                    |
| PEPPERMINT OIL (UNII: AV092KU4JH)                      |  |   |                      |                    |
| METHYLPARABEN (UNII: A2I8C7HI9T)                       |  |   |                      |                    |
| METHYL SALICYLATE (UNII: LAV5U5022Y)                   |  |   |                      |                    |
| DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)                    |  |   |                      |                    |
| POLYSORBATE 80 (UNII: 6OZP39ZG8H)                      |  |   |                      |                    |
| PROPYLPARABEN (UNII: Z8IX2SC1OH)                       |  |   |                      |                    |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)                    |  |   |                      |                    |
| TROLAMINE (UNII: 9O3K93S3TK)                           |  |   |                      |                    |
| Packaging  |  |   |                      |                    |
| #  | Item Code                                | Package Description                                 | Marketing Start Date | Marketing End Date |
| 1  | NDC:51452-450-16                         | 475 mL in 1 JUG; Type 0: Not a Combination Product  | 02/26/2024           |                    |
| 2  | NDC:51452-450-01                         | 3800 mL in 1 JUG; Type 0: Not a Combination Product | 02/26/2024           |                    |
| Marketing Information                                  |  |   |                      |                    |
| Marketing Category                                     | Application Number or Monograph Citation | Marketing Start Date                                | Marketing End Date   |                    |
| OTC Monograph Drug                                     | M017                                     | 02/26/2024  |                      |                    |

**Labeler** - FABRICATION ENTERPRISES (070577218)

Revised: 2/2024

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