

COLD THERAPY PAIN RELIEF- menthol 10.5% spray

Kroger

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.

Drug Facts

Active ingredient

Menthol 10.5%.....

Purpose

Topical Analgesic

Uses Temporary relief from minor aches and pains of sore muscles and joints associated with arthritis, backache, strains and sprains

Warnings

For external use only.

Flammable: Do not use while smoking or near heat or flame.

When using this product • avoid contact with the eyes or mucous membranes • do not apply to wounds or damaged skin • do not apply to the irritated skin • do not bandage • wash hands after use with cool water • do not use with heating pad or device

Stop use and ask a doctor if • condition worsens, or if symptoms persist for more than 7 days, or clear up and reoccur.

Keep out of reach of children. If accidentally ingested get medical help or contact a Poison Control Center immediately

Directions • Adults and children 2 years of age and older: Apply to affected area not more than 3 to 4 times daily. • Children under 2 years of age: Consult physician.

Inactive ingredients Alcohol Denat., Arnica Montana Flower Extract, Calendula Officinalis Flower Extract, Camellia Sinensis Leaf Extract, Chamomile Recutita Flower Extract, Dimethyl Sulfone, Echinacea Angustifolia Extract, Ilex Paraguariensis Leaf Extract, Isopropyl Myristate, Juniperus Communis Fruit Extract, Water

Questions or comments? 1-800-632-6900

COMPARE TO the active ingredient of **BIOFREEZE®**

*See back of can



Cold Therapy Pain Relief Spray

**Menthol 10.5%
Topical Analgesic**

- For the Temporary Relief of Minor Aches and Pains of Muscles and Joints

NET WT 3 OZ (85g)

Drug Facts

Active ingredient **Purpose**
Menthol 10.5%.....Topical Analgesic

Uses Temporary relief of minor aches and pains of muscles and joints associated with arthritis, simple backache, strains and sprains.

Warnings

For external use only.

Flammable: Do not use while smoking or near heat or flame.

When using this product • avoid contact with the eyes or mucous membranes • do not apply to wounds or damaged skin • do not apply to the irritated skin or if excessive irritation develops • do not bandage • do not use with heating pad or device

Stop use and ask a doctor if • condition worsens, or if symptoms persist for more than 7 days, or clear up and occur again within a few days.

If pregnant or breastfeeding ask a health professional before use.

Keep out of reach of children. If accidentally ingested get medical help or contact a Poison Control Center immediately.

Directions • **Adults and children 2 years of age and older:** Spray on to the affected areas not more than 3-4 times daily. • **Children under 2 years of age:** Consult physician.

Other information Store in a cool dry place with lid closed tightly

Inactive ingredients Alcohol Denat., Arnica Montana Flower Extract, Calendula Officinalis Flower Extract, Camellia Sinensis Leaf Extract, Chamomilla Recutita (Matricaria) Flower Extract, Dimethyl Sulfone, Echinacea Angustifolia Extract, Ilex Paraguariensis Leaf Extract, Isopropyl Myristate, Juniperus Communis Fruit Extract, Water.

Questions or comments? 1-800-632-6900

DISTRIBUTED BY THE KROGER CO.
CINCINNATI, OHIO 45202

QUALITY GUARANTEE
800-632-6900 • www.kroger.com

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COLD THERAPY PAIN RELIEF

menthol 10.5% spray

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:59450-777 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|-----------------|
| Menthol (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) | Menthol | 10.5 g in 100 g |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| Alcohol (UNII: 3K9958V90M) | |
| ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ) | |
| CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD) | |
| GREEN TEA LEAF (UNII: W2ZU1RY8B0) | |

| | |
|--|--|
| CHAMOMILE (UNII: FGL3685T2X) | |
| Dimethyl Sulfone (UNII: 9H4PO4Z4FT) | |
| ECHINACEA ANGUSTIFOLIA (UNII: VB06AV5US8) | |
| ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F) | |
| Isopropyl Myristate (UNII: 0RE8K4LNJS) | |
| JUNIPER BERRY (UNII: O84B5194RL) | |
| Water (UNII: 059QF0K00R) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:59450-777-03 | 85 g in 1 CAN; Type 0: Not a Combination Product | 04/03/2018 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part348 | 04/03/2018 | |

Labeler - Kroger (006999528)

Registrant - Product Quest Mfg. (927768135)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------------------|---------|-----------|---|
| Product Quest Mfg. | | 927768135 | manufacture(59450-777) , label(59450-777) |

Revised: 7/2018

Kroger