

COOL AND HEAT- menthol 16% spray

Top Care

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 16%

Purpose

Topical analgesic

Uses

- temporarily relief of pain and itching associated with:
- arthritis • simple backache • muscle strains • bruises • cramps • muscle sprains

Warnings

For external use only

Flammable

- do not use while smoking or near heat or flame
- avoid long term storage above 104^oF
- do not puncture or incinerate. Contents under pressure
- do not store at temperature above 120^oF

When using this product

- avoid contact with eyes and mucous membranes
- do not apply to wounds or damages skin
- do not bandage tightly
- use only as directed

Stop use and ask a doctor if

- condition worsens
- symptoms last more than 7 days or clear up and occur again within a few days
- needed for longer than 1 week

Keep out of reach of the children. If swallowed, get medical help or contact a Poison Control Center right away

If pregnant or breast-feeding, ask a health professional before use.

Directions

- shake well
- adults and children 12 years of age and older: spray on affected area, not more than 3 to 4 times daily
- children under 12 years of age: consult a doctor

Inactive ingredients

Glycerin, Propylene Glycol, SD Alcohol 40, Water

Drug Facts

| Active ingredient | Purpose |
|--------------------|-------------------|
| Menthol 16.0%..... | Topical analgesic |

Uses • temporarily relieves minor pain associated with:
 • arthritis • simple backache • muscle strains • bruises
 • muscle sprains

Warnings
 For external use only.

Flammable • do not use while smoking or near heat or flame
 • avoid long term storage above 104°F.
 • do not puncture or incinerate. Contents under pressure.
 • do not store at temperatures above 120°F.

When using this product • avoid contact with eyes and mucous membranes • do not apply to wounds or damaged skin
 • do not bandage tightly • use only as directed

Stop use and ask doctor if • condition worsens • symptoms persist for more than 7 days or clear up and occur again within a few days • needed for longer than 1 week

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

Directions • shake well • adults and children 12 years of age and older: spray product on affected area, not more than 3 to 4 times daily. • children under 12 years of age: consult a doctor.

Inactive ingredients Glycerin, Propylene Glycol, SD Alcohol 40 (55%), Water.

*This product is not manufactured or distributed by Chatterm, owner of registered trademark IcyHot®

TopCare®

Cool & Heat

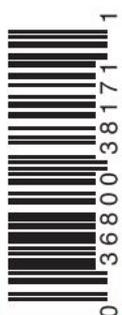
QUICK DRYING

SORE MUSCLE MEDICATED SPRAY
 16% - MENTHOL / TOPICAL ANALGESIC
 Continuous Spray

Relief Therapy for:

- Arthritis
- Backache Muscle Strains & Sprains

DISTRIBUTED BY
 TOPCO ASSOCIATES LLC
 ELK GROVE VILLAGE, IL 60007
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 QUESTIONS? 1-888-423-0139
 topcare@topco.com



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Compare to Icy Hot® active ingredient*

NET WT 4 OZ (113 g)

COOL AND HEAT

menthol 16% spray

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:36800-730 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|---------------|
| MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) | MENTHOL | 16 g in 100 g |

Inactive Ingredients

| Ingredient Name | Strength |
|-----------------------------|----------|
| Glycerin (UNII: PDC6A3C0OX) | |

Propylene Glycol (UNII: 6DC9Q167V3)

Alcohol (UNII: 3K9958V90M)

Water (UNII: 059QF0K00R)

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:36800-730-04 | 113 g in 1 CAN; Type 0: Not a Combination Product | 01/22/2013 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part348 | 01/22/2013 | |

Labeler - Top Care (006935977)

Registrant - Product Quest Mfg (927768135)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------|---------|-----------|---|
| Product Quest Mfg | | 927768135 | manufacture(36800-730) , label(36800-730) |

Revised: 7/2018

Top Care