

CVS COLD AND HOT- menthol 16% spray

CVS

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.

CVS cold and Hot Spray

Menthol 16%

Topical analgesic

Temporarily alleviates minor aches and pains of muscles and joints associated with Arthritis

Simple Backache

Strains

Bruises

Cramps

For external use only

Flammable:

Do not use while smoking or near heat or flames. Avoid longterm storage above 104°F. Do not punctuate or incinerate. Contents under pressure. Do not store at temperatures above 120°F.

When using this product use only as directed

Read and follow all directions and warnings on this label

Do not allow contact with eyes and mucous membranes

Rare cases of serious burns have been reported with products of this type

Do not apply to wounds or damaged, broken or irritated skin

Do not bandage or apply local heat (such as heating pads) or medicated patch to the area of use

A transient burning sensation may occur upon application but generally disappears in several days

If severe burning sensations occurs, discontinue use immediately

Do not expose the area treated with product to heat or direct sunlight

Avoid applying into skin folds

Stop use and ask doctor if condition worsens, redness is present, irritation develops or symptoms persist for more than 7 days or clear up and occur again within few days. Do not use for longer than 1 week.

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

Control Center immediately (1-800-222-1222).

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

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.

Glycerin, Isobutane, Propylene Glycol, SD Alcohol 40B (29%), Water



Compare to the active ingredient in Icy Hot® Medicated Spray*

Cold & Hot Dry Spray
MEDICATED PAIN RELIEF
MENTHOL 16%

- Cold & hot therapy for pain
- Long-lasting quick-dry formula
- For muscles & joints

SPRAYS AT ANY ANGLE

NET WT 4 OZ (113 g)



*This product is not manufactured or distributed by Chatterm, Inc., owner of the registered trademark Icy Hot®.

Drug Facts

| Active ingredient | Purpose |
|-------------------|-------------------|
| Menthol 16% | Topical analgesic |

Uses
 Temporarily alleviates minor aches and pains of muscles and joints associated with: ■ Arthritis ■ Simple Backache ■ Strains ■ Bruises ■ Sprains ■ Cramps

Warnings:
For external use only.
Flammable: Do not use while smoking or near heat or flames. 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 use only as directed ■ Read and follow all directions and warnings on this label ■ Do not allow contact with the eyes and mucous membranes ■ Rare cases of serious burns have been reported with products of this type ■ Do not apply to wounds or damaged, broken or irritated skin ■ Do not bandage or apply local heat (such as heating pads) or a medicated patch to area of use ■ A transient burning sensation may occur upon application but generally disappears in several days ■ If severe burning sensation occurs, discontinue use immediately ■ Do not expose the area treated with product to heat or direct sunlight ■ Avoid applying into skin folds
Stop use and ask doctor if condition worsens, redness is present, irritation develops or symptoms persist for more than 7 days or clear up and occur again within a few days. Do not use for longer than 1 week.
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Inactive ingredients:
 Glycerin, Isobutane, Propylene Glycol, SD Alcohol-40B (29%), Water

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 CVS Pharmacy, Inc. DDT 2Q M5655
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 Woonsocket, RI 02896
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#365469

1 85549 82705
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menthol 16% spray

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:51316-899 |
| 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 |
|--|-----------------|
| WATER (UNII: 059QF0KO0R) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| ISOBUTANE (UNII: BXR49TP611) | |
| DEHYDRATED ALCOHOL (UNII: 3K9958V90M) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|----------|------------------|---|-----------------------------|---------------------------|
| 1 | NDC:51316-899-16 | 113 g in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product | 09/08/2022 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------------|---|-----------------------------|---------------------------|
| OTC monograph not final | part348 | 09/08/2022 | |

Labeler - CVS (062312574)

Revised: 9/2022

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