COLD AND HOT NO MESS MEDICATED- menthol, unspecified form spray Natural Essentials, Inc.

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

- relieves minor pain of muscles and joints associated with:
 - arthritis
 - simple backache
 - strains
 - bruises
 - sprains

Warnings

For external use only

Flammable:

• Do not use while smoking or near heat or flame

Do not apply

- to wounds or damaged, broken or irritated skin.
- Do not allow contact with eyes or mucous membranes.

When using this product

- keep out of eyes
- do not bandage tightly
- do not use with a heating pad
- use only as directed
- do not puncture or incinerate. Contents under pressure. Do not store at temperatures above 120°F.

Stop use and ask a 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 a week

If pregnant or breast-feeding,

• ask a health professional before use.

Keep out of reach of children and pets.

• If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- shake well
- adults and children 12 years of age and older:
- spray product on area not more than 1 to 3 times daily
- children under 12 years of age
- ask a doctor

Other information

• May cause staining. Use with caution when spraying near fabric and unprotected surfaces

Inactive ingredients

Glycerin, Propylene Glycol, SDA 40-2 Alcohol, Water.

Principal Display Panel - 4 oz Can Label

CVS HealthTM

Compare to the active ingredient in IcyHot® Pain Relief Spray*

Cold & Hot

MENTHOL 16%

No Mess Medicated Spray

Topical analgesic

SPRAYS AT ANY ANGLE

- Pain relief therapy for arthritis, backache, muscle strains & sprains
- Non-greasy
- Quick drying

NET WT 4 0Z (113 g)





NET WT 4 OZ (113 g)

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Directions ■ shake well

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 spray product on area not more than 1 to 3 times daily = children under 12 years of age = ask a doctor
- Other information May cause staining. Use with caution when

spraying near fabric and unprotected surfaces

Inactive ingredients Glycerin, Propylene Glycol, SDA 40-2 Alcohol,

*This product is not manufactured or distributed by Chattem, Inc., owner of the registered trademark lcyHot®

COLD AND HOT NO MESS MEDICATED

menthol, unspecified form spray

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:66902-856

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength MENTHOL, UNSPECIFIED FORM (UNII: L7T10 EIP3A) (MENTHOL, UNSPECIFIED FORM -MENTHOL, UNSPECIFIED 160 mg UNII:L7T10EIP3A) in 1 g

Inactive Ingredients Ingredient Name Strength ALCOHOL (UNII: 3K9958V90M) GLYCERIN (UNII: PDC6A3C0OX) PROPYLENE GLYCOL (UNII: 6DC9Q167V3) WATER (UNII: 059QF0KO0R)

	Packaging							
l	# Item Code	Package Description	Marketing Start Date	Marketing End Date				
l	1 NDC:66902-856-04	118 g in 1 CAN; Type 0: Not a Combination Product	10/06/2020					
П								

Marketing Information							
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date				
OTC monograph not final	part348	10/06/2020					

Labeler - Natural Essentials, Inc. (947484713)

Establishment								
Name	Address	ID/FEI	Business Operations					
NATURAL ESSENTIALS, INC.		947484713	MANUFACTURE(66902-856)					

Revised: 10/2020 Natural Essentials, Inc.