

**CVS HEALTH COLD AND HOT ROLL-ON MENTHOL - menthol, unspecified form liquid
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:

- temporarily relieves minor pain associated with:
 - arthritis
 - simple backache
 - muscle strains
 - sprains
 - bruises
 - cramps

Warnings:

For external use only.

When using this product

- use only as directed. Read and follow all directions and warnings on this label.
- rare cases of serious burns have been reported with products of this type
- do not bandage tightly or apply local heat (such as heating pads) or medicated patch to the area of use
- avoid contact with eyes or mucous membranes
- do not apply to wounds or damaged, broken or irritated skin
- 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 a doctor if

- condition worsens
- redness is present
- irritation develops
- symptoms persist for more than 7 days or clear up and occur again within a few days
- you experience signs of skin injury, such as pain, swelling, or blistering where the product was applied.

Flammable

- Keep away from fire or flame.

If pregnant or breast-feeding,

- Ask a health professional before use.

Keep out of reach of children

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

Directions: adults and children over 12 years:

- apply a thin layer to affected area
- massage into painful area until thoroughly absorbed into skin
- repeat as necessary, but no more than 3 to 4 times daily
- **IF MEDICINE COMES IN CONTACT WITH HANDS, WASH WITH SOAP AND WATER**

Children 12 years or younger

- ask a doctor

Other information:

Store in a cool dry area. Close cap tightly after use.

Inactive Ingredients

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aminomethyl Propanol, Capsaicin, Deionized Water, Glycerin, Isopropyl Myristate, Propylene Glycol, SDA 40-2 Alcohol.

Principal Display Panel - Cold & Hot Roll-On Menthol 16% Box Label**CVS**

Health™

Compare to the active
ingredient in Maximum
Strength IcyHot®
Pain Relieving Liquid

MAXIMUM STRENGTH**Cold & Hot
Roll-On****MENTHOL 16%****Pain-relieving liquid**

- Long-lasting formula
- No-touch applicator
- Dries quickly

Actual Product Size
on Side Panel

2.5 FL OZ (73 mL)



Principal Display Panel - Cold & Hot Roll-On Menthol 16% Container Label

**CVS
Health™**

MAXIMUM STRENGTH

**Cold & Hot
Roll-On**

MENTHOL 16%

Pain-relieving liquid

- Long-lasting formula
- No-touch applicator
- Dries quickly

2.5 FL OZ (73 mL)

CVS Health

MAXIMUM STRENGTH
Cold & Hot
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MENTHOL 16%
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 Money Back Guarantee

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CVS HEALTH COLD AND HOT ROLL-ON MENTHOL

menthol, unspecified form liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66902-241
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
CAPSAICIN (UNII: S07O44R1ZM)	
WATER (UNII: 059QF0K00R)	
GLYCERIN (UNII: PDC6A3C0OX)	

ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ALCOHOL (UNII: 3K9958V90M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66902-241-25	1 in 1 BOX	01/17/2018	
1		73 mL in 1 CONTAINER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	01/17/2018	

Labeler - NATURAL ESSENTIALS, INC. (947484713)

Establishment

Name	Address	ID/FEI	Business Operations
NATURAL ESSENTIALS, INC.		947484713	MANUFACTURE(66902-241)

Revised: 1/2019

NATURAL ESSENTIALS, INC.