CVS HEALTH ROLL-ON FOOT PAIN RELIEF- menthol, unspecified form gel 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 4%

Purpose

Topical Analgesic

Uses

For the temporary relief of minor aches and pains of muscles and joints associated with:

- Simple backache
- Arthritis
- Strains
- Bruises
- Sprains

Warnings

For external use only

Flammable: Keep away from fire or flame and heated surfaces

Do not use

- if you are allergic to any ingredient in this product
- on open wounds, damaged or irritated skin
- with a heating pad or TENS device

When using this product

- do not bandage tightly
- do not use otherwise than as directed
- avoid contact with eyes or mucous membranes
- rare cases of burns have been reported with products of this type
- if severe burning sensation occurs, discontinue use immediately

Stop use and ask a doctor if

- condition worsens
- rash, itching, redness or excessive irritation of the skin develops

- symptoms persist for more than 7 days
- symptoms clear up and occur again within a few days

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 12 years of age and over:

- apply to affected area using roller ball not more than 4 times daily
- massage painful area until absorbed into skin
- wash hands after each use with cold water

Children under 12 years of age:

consult a doctor

Other information

- store in a cool place away from direct sunlight
- store with cap closed tightly

Inactive ingredients

Aloe Barbadensis Leaf Extract, Arctium Lappa Root Extract, Arnica Montana (Arnica Flower) Extract, Boswellia Serrata Extract, Calendula Officinalis (Calendula) Flower Extract, Camelia Sinensis (Green Tea) Extract, Camphor, Carbomer 940, FD&C Blue #1, FD&C Yellow #5, Glycerin, Isopropyl Alcohol, Isopropyl Myristate, Organic Ilex Paraguariensis Leaf Extract, Tocopheryl Acetate, Triethanolamine, Silicone Dioxide, Water.

Principal Display Panel - 74 mL Bottle Label

CVS

Health®

Roll-On Foot Pain Relief

MENTHOL 4%

- Temporarily relieves painful, achy feet
- Soothes aggravated nerves

2.5 FL OZ (74 mL)



CVS HEALTH ROLL-ON FOOT PAIN RELIEF

menthol, unspecified form gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66902-919
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety Ingredient Name Basis of Strength MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A) MENTHOL, UNSPECIFIED FORM UNSPECIFIED FORM in 1 mL

Inactive Ingredients		
Ingredient Name	Strength	
ALOE VERA LEAF (UNII: ZY81Z83H0X)		
ARCTIUM LAPPA ROOT (UNII: 597E9BI3Z3)		
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)		
INDIAN FRANKINCENSE (UNII: 4PW41QCO2M)		
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)		
GREEN TEA LEAF (UNII: W2ZU1RY8B0)		

CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
GLYCERIN (UNII: PDC6A3C0OX)
ISOPROPYL ALCOHOL (UNII: ND2M416302)
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)
SILICON DIOXIDE (UNII: ETJ7Z 6XBU4)
.ALPHATOCOPHEROL (UNII: H4N855PNZ1)
TROLAMINE (UNII: 903K93S3TK)
WATER (UNII: 059QF0KO0R)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66902-919- 03	74 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/12/2020	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part348	03/12/2020		

Labeler - NATURAL ESSENTIALS, INC. (947484713)

Establishment					
Name	Address	ID/FEI	Business Operations		
NATURAL ESSENTIALS, INC.		947484713	MANUFACTURE(66902-919)		

Revised: 7/2021 NATURAL ESSENTIALS, INC.