CVS HEALTH 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

- Use only as directed
- do not bandage tightly
- avoid contact with eyes or mucous membranes

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, Camellia Sinensis (Green Tea) Extract, Camphor, Caprylic/Capric Triglyceride, Carbomer, 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_®

Compare to the active ingredient in Biofreeze® Pain Relief Roll-On*

Pain Relief Roll-On

MENTHOL 4%

- Fast-acting pain relief
- Relieves muscle pain
- Soothes aggravated nerves
- Vanishing scent

2.5 FL OZ (74 mL)



Principal Display Panel - 89 mL Tube Label

CVS

Health_®

Compare to the active ingredient in Biofreeze® Pain Relief Gel*

Pain Relief Gel

MENTHOL 4%

- Fast-acting pain relief
- Relieves muscle pain
- Soothes aggravated nerves
- Vanishing scent

3 FL OZ (89 mL)



Pain Relief Gel

MENTHOL 4%

- Fast-acting pain relief
- Relieves muscle pain
- Soothes aggravated nerves
- Vanishing scent



3 FL OZ (89 mL)

Drug Facts

Active ingredient

Purpose

Menthol 4%.....

.Topical Analgesic

Uses: Temporary relief from minor aches and pains of sore muscles and joints associated with: arthritis, backache, strains, sprains

Warnings

For external use only

Flammable: Keep away from excessive heat or open flame

When using this product

Use only as directed

- Avoid contact with eyes or mucous membranes
- Do not apply to wounds or damaged skin.
- Do not use with other ointments, creams, sprays, or liniments.
- Do not apply to irritated skin or if excessive skin irritation develops.
- Do not bandage
- Wash hands after use with cool water
- Do not use with heating pad or device.
- Store in a cool, dry place

Stop use and ask a doctor if

 Condition worsens, or if symptoms persist for more than 7 days, or clear up and recur

If pregnant or breast feeding, ask a physician before use. Keep out of reach of children and pets. If swallowed, seek professional help and contact Poison Control Center right away.

Directions

Adults and children 2 years of age and older: apply over affected areas not more than 4 times daily; massage as

Children under 2 years of age! Consult physician

Inactive ingredients

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

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CVS HEALTH PAIN RELIEF

menthol, unspecified form gel

Product Information

	Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66902-920
ı	Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
MENTHOL, UNSPECIFIED FORM (UNII: L7T10 EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10 EIP3A)	MENTHOL, UNSPECIFIED FORM	36 mg in 1 mL		

Inactive Ingredients		
Ingredient Name	Strength	
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)		
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: 0 RE8 K4LNJS)		
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)		
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)		
.ALPHATO COPHEROL (UNII: H4N855PNZ1)		
TROLAMINE (UNII: 903K93S3TK)		
WATER (UNII: 059QF0KO0R)		

]	Packaging				
7	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
	NDC:66902-920-03	74 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/20/2021		
2	NDC:66902-920-04	89 mL in 1 TUBE; Type 0: Not a Combination Product	01/20/2021		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part348	01/20/2021		

Labeler - NATURAL ESSENTIALS, INC. (947484713)

Establishment				
Name	Address	ID/FEI	Business Operations	

NATURAL ESSENTIALS, INC.

947484713 MANUFACTURE(66902-920)

NATURAL ESSENTIALS, INC. Revised: 1/2021