

COOLING EPSOM RUB- menthol granule, for solution
CVS Pharmacy, 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.

CVS 403.002-403AC

Active ingredients

Menthol (1.25% w/w)

Purpose

Topical analgesic

Use

For the temporary relief of minor aches and pains of muscle joints associated with simple backache, arthritis, strains, bruises and sprains

Warnings

For external use only

Flammable

- keep away from fire or flame, heat, spark, electrical

when using this product

- avoid contact with the eyes
- do not apply to wounds or damaged skin
- do not bandage tightly

Stop use and ask a doctor if

condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days

Keep out of reach of children

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

Directions

adults children 2 years of age and older - apply to affected area not more than 3 to 4 times daily

children under 2 years of age - consult a doctor

Directions for use as Relaxing Soak Solution:

For external use only. Pour liberally into warm water no more than 4 times daily.

Caution: If prompt relief is not obtained or there is evidence of infection, discontinue use and consult

your physician. Individuals with diabetes should not use hot or warm water soaks unless advised by a physician. **Keep out of reach of children**

Other information

- does not contain, nor is intended as a substitute for grain or ethyl alcohol
- will produce serious gastric disturbances if take internally
- fumes can be acutely irritating to respiratory system. Avoid inhaling this product

Inactive ingredients

water, isopropyl alcohol, Capsicum Frutescens fruit extract, methyl salicylate, magnesium sulfate, blue 1

Adverse Reactions

Distributed by: CVS Pharmacy, Inc.

One CVS Drive, Woonsocket, RI 02895

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CVS.com

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494.000/494AA

principal display panel

CVS

Health

Menthol

Cooling

Epsom Rub

PAIN RELIEVING

SOAKING SOLUTION

Temporarily relieves pain associated with:

- Arthritis
- Minor aches
- Sprains
- Tired feet

16 FL OZ (1 PT) 473 mL



COOLING EPSOM RUB

menthol granule, for solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59779-071
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
menthol (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	menthol	11.7 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0KO0R)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
CAPSICUM (UNII: 00UK7646FG)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
MAGNESIUM SULFATE, UNSPECIFIED (UNII: DE08037SAB)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59779-071-43	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/05/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	05/05/2015	

Labeler - CVS Pharmacy, Inc (062312574)

Registrant - Vi-Jon, Inc (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, Inc		790752542	manufacture(59779-071)

Revised: 5/2020

CVS Pharmacy, Inc