

ACTIVICE- menthol liquid
Medline Industries

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.

ActivICE roll-on

Active Ingredient

Menthol 8.0%

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.

Avoid contact with eyes.

Flammable: keep away from fire or flame.

When using this product

- use only as directed
- do not bandage tightly or use with heating pad
- do not apply to wounds or damaged skin

Stop use and ask doctor if

- condition worsens, or if symptoms
- persist for more than 7 days or clear
- up and occur again within a few days
- redness is present
- excessive irritation of the skin develops

If pregnant or breastfeeding,

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:

roll directly onto affected area without the need to rub, massage or bandage
repeat if necessary, but do not apply more than 4 times daily.

Children 12 years or younger:

ask a doctor.

Other information

- Store at room temperature.

Inactive Ingredients

boswellia serrata extract, carbomer, dimethylsulfone(MSM), eucalyptus oil, glucosamine sulfate, glycerin, peppermint oil, SD alcohol 39C, triethanolamine, water.

<p>Drug Facts</p> <p>Active ingredient Purpose Menthol 8.0% Topical Analgesic</p> <p>Uses For the temporary relief of minor aches and pains of muscles and joints associated with: ■ simple backache ■ arthritis ■ strains ■ bruises ■ sprains</p> <p>Warnings For external use only. Avoid contact with eyes. Flammable: keep away from fire or flame. When using this product ■ use only as directed ■ do not bandage tightly or use with heating pad ■ do not apply to wounds or damaged skin Stop use and ask doctor if ■ condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days ■ redness is present ■ excessive irritation of the skin develops If pregnant or breastfeeding, ask a health professional before use.</p>	<p> NDC 53329-992-69 ROLL-ON</p> <p>ActivICE™</p> <p>TEMPORARY PAIN RELIEF</p> <ul style="list-style-type: none">➕ Arthritis➕ Muscle Aches➕ Joint & Back Pain <p>Compare to Biofreeze®*</p>  <p>3 FLOZ (88 mL)  Cooling Menthol</p>	<p>Drug Facts (Continued)</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p> <p>Directions Adults and children over 12 years: ■ roll directly onto affected area without the need to rub, massage or bandage ■ repeat if necessary, but do not apply more than 4 times daily. Children 12 years or younger: ask a doctor.</p> <p>Other Information ■ Store at room temperature.</p> <p>Inactive Ingredients boswellia serrata extract, carbomer, dimethylsulfone(MSM), eucalyptus oil, glucosamine sulfate, glycerin, peppermint oil, SD alcohol 39C, triethanolamine, water.</p> <p><small>MDSAICEROLL</small> Not made with Natural Rubber Latex. Keep product upright. Handle with care. Protect from freezing, avoid excessive heat. www.medline.com Manufactured in USA for: Medline Industries, Inc., Three Lakes Drive, Northfield, IL 60093 1-800-MEDLINE R519 MFD 2-530 Rev 01 *This product is not manufactured or distributed by Performance Health and/or its subsidiaries, owner of the registered trademark Biofreeze®.</p>  <p>8 88277 69819 5</p>
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menthol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53329-992
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	80 g in 1000 g

Inactive Ingredients

Ingredient Name	Strength
BOSWELLIA SERRATA RESIN OIL (UNII: 5T1XCE6K8K)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
WATER (UNII: 059QF0KO0R)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
ALCOHOL (UNII: 3K9958V90M)	
GLUCOSAMINE SULFATE (UNII: 1FW7WLR731)	
TROLAMINE (UNII: 9O3K93S3TK)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53329-992-69	85 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/04/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC mono graph not final	part348	03/04/2019	

Labeler - Medline Industries (025460908)

Establishment

Name	Address	ID/FEI	Business Operations
Troy Manufacturing, Inc.		160075248	manufacture(53329-992)