

ACTIVICE- menthol spray
Medline Industries, 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.

ActivICE™ Extra Strength Temporary Pain Relief, Spray

Active ingredient

Menthol 10.0%

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

Do not puncture or incinerate. Contents under pressure.

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:

- spray 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, dimethylsulfone (MSM), eucalyptus oil, glucosamine sulfate, glycerine, SD alcohol 39C, PEG-8 dimethicone, pentylene glycol, peppermint oil, water (USP)

Manufacturing information

REF: MDSAICESPRY4

Not made with Natural Rubber Latex.

www.medline.com Manufactured in USA for: Medline Industries, Inc.

Three Lakes Drive, Northfield, IL 60093 **1-800MEDLINE**

*This product is not manufactured or distributed by Performance Health and/or its subsidiaries, owner of the registered trademark Biofreeze®.

Package Label

REF MDSAICESPRY4

M 5655 DOT-SP 20590

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** RK19MFO 2-536 Rev 00

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ACTIVICE
menthol spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53329-996
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	100 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
PEPPERMINT OIL (UNII: AV092KU4JH)	
INDIAN FRANKINCENSE (UNII: 4PW41QCO2M)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
GLUCOSAMINE SULFATE (UNII: 1FW7WLR731)	
ALCOHOL (UNII: 3K9958V90M)	
PEG-8 DIMETHICONE (UNII: GIA7T764OD)	
GLYCERIN (UNII: PDC6A3C0OX)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
WATER (UNII: 059QF0KO0R)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53329-996-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	01/01/2020	

Labeler - Medline Industries, Inc. (025460908)**Establishment**

Name	Address	ID/FEI	Business Operations
Troy Manufacturing, Inc.		160075248	manufacture(53329-996)