ACTIVICE- menthol spray
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 spray

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.

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 a 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 helop 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

citric acid, dimethylsulfone (MSM), eucalyptus oil, glucosamine sulfate, peppermint oil, SD alcohol 39C, water.

ACTIVICE

menthol spray

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:53329-991
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**
PEPPERMINT OIL (UNII: AV092KU4JH)	
WATER (UNII: 059QF0KO0R)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
ALCOHOL (UNII: 3K9958V90M)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
GLUCOSAMINE SULFATE (UNII: 1FW7WLR731)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53329-991-04	113.4 g in 1 BOTTLE, SPRAY; 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 monograph not final	part348	03/04/2019	

Labeler - Medline Industries (025460908)

Establishment

Name	Address	ID/FEI	Business Operations
Troy Manufacturing		160075248	manufacture(53329-991)

Revised: 11/2019 Medline Industries