

FLEXACURE- menthol spray

Symedic LLC

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.

Menthol USP 2.25%

Apply as needed.

(for external use only)

When using this product

- use only as directed
- do not bandage tightly or use with heating pad
- avoid contact with eyes or mucous membranes
- do not apply to wounds or damaged skin

Stop use and ask a doctor if • condition worsens • symptoms persist for more than 7 days or clear up and occur again within a few days • redness is present • irritation develops

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.

adults and children 12 years of age and older:

- apply generously to affected area • massage into painful area until thoroughly absorbed into skin • repeat if necessary, but not more than 3 to 4 times daily

children under 12 years of age: ask a doctor

Arnica Montana Flower Extract, Chondroitin Sulfate, Dimethyl Sulfone USP (MSM), Dimethyl Sulfoxide USP (DMSO), Glucosamine HCL (Shellfish), Glycerin, Hydrogen Peroxide, Magnesium Chloride, Propylene Glycol, Water (Aqua)

Persons with a known allergy to shellfish or sulfur should not use this product

Dist. by: Symedic LLC Las Vegas, NV 89147

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www.flexacure.com

Uses: Temporarily relieves minor pain associated with:

- arthritis • simple backache • muscle strains
- sprains • bruises • cramps

Topical Analgesic

Active Ingredients	Purpose
Menthol USP 2.25%	Topical Analgesic

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FLEXACURE

menthol spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71402-007
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	2.25 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
DIMETHYL SULFOXIDE (UNII: YOW8V9698H)	
GLYCERIN (UNII: PDC6A3C0OX)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	
CHONDROITIN SULFATE (BOVINE) (UNII: 6IC1M3OG5Z)	
DIMETHYL SULFATE (UNII: JW5CW40Z50)	
GLUCOSAMINE HYDROCHLORIDE (UNII: 750W5330FY)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71402-007-01	29 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	10/14/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	10/14/2019	

Labeler - Symedic LLC (060844542)