PAIN RELIEF- menthol spray Sagely Enterprises 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.

Pain Relief Spray

Active ingredient

Menthol 10%

Purpose

Menthol 10%.....Topical Analgesic

Uses

temporarily relieves the minor aches and pains of muscles and joints associated with:

- strains
- bruises
- simple backache
- arthritis
- sprains

Warnings

For external use only.

Do not use

- on wounds or damaged, broken, or irritated skin
- with a heating pad

When using this product

- avoid contact with eyes or mucous membranes
- do not bandage tightly

Stop use and ask a doctor if

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

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

- Use only as directed
- Adults and children 12 years of age and older: apply to affected area not more than 3 to 4 times daily
- Children under 12 years of age: ask a doctor

Inactive ingredients

SD Alcohol 40-B, Water, Sambucus Nigra Fruit Extract, Boswellia Serrata Extract, Camphor, Mentha Piperita Oil, Glycerin, Arnica Montana Flower Extract

Sagely Naturals

Extra Strength

Pain Relief Spray

95% Natural Ingredients

Instant Cooling

with 10% Menthol

2 Fl Oz / 60 mL







menthol spray

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:82075-430

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	10 g in 100 g

Inactive Ingredients		
Ingredient Name	Strength	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)		
ALCOHOL (UNII: 3K9958V90M)		
WATER (UNII: 059QF0KO0R)		
INDIAN FRANKINCENSE (UNII: 4PW41QCO2M)		
EUROPEAN ELDERBERRY (UNII: BQY1UBX046)		
MENTHA PIPERITA (UNII: 79M2M2UDA9)		
CAMPHOR (NATURAL) (UNII: N20HL7Q941)		
GLYCERIN (UNII: PDC6A3C0OX)		

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82075- 430-30	1 in 1 CARTON	11/19/2021	
1		60 g in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	11/19/2021	

Labeler - Sagely Enterprises Inc. (117049032)

Establishment				
Name	Address	ID/FEI	Business Operations	
PakLab		078717086	manufacture(82075-430)	

Revised: 12/2021 Sagely Enterprises Inc.