SUNMED TOPICAL WITH MENTHOL- menthol spray Sunflora 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.

SUNMED Topical Spray with MENTHOL

Active ingredient

Menthol 10.5%

Menthol 10.4% Topical Analgesic

Uses Temporary relief from minor aches and pains of muscles and joints associated with, arthritis, simple backache, strains, bruises, sprains.

For external use only

When using this product, avoid contact with eyes and mucous membranes., do not apply to wound or damage skin, do not bandage, do not use with heating pad or device.

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.

Keep out of reach of children, if swallowed, get medical help or contact a Poison Control Center right away.

Adults and children 2 years of age and older: Apply to affected area no more than 3 to 4 times daily. Wash hands with soap. Children under 2 years of age: consult a doctor.

INACTIVE INGREDIENTS

Aloe Barbadensis Leaf Extract

Arctium Lappa Root (Burdock) Extract

Arnica Montana Flower Extract

Boswellia Carterii Resin Extract

Calendula Officinalis Extract

Camellia Sinensis Leaf Extract

Camphor

Carbomer

FD&C Blue #1

FD&C Yellow #5

Full Spectrum Industrial Hemp Extract

Glycerin

Ilex Paraguariensis (Mate) Leaf Extract

Isopropyl Alcohol

Isopropyl Myristate

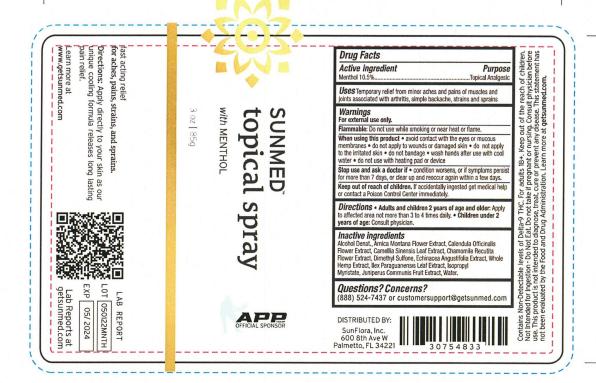
Melissa Officinalis (Lemon Balm) Leaf Extract

Silica

Tocopheryl Acetate

Triethanolamine

Water



Trim Line
Text Safe Line
Bleed Line

menthol spray

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:73240-903

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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	Ingredient Name	Basis of Strength	Strength	
	MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	10.5 g in 100 g	

Inactive Ingredients		
Ingredient Name	Strength	
ECHINACEA ANGUSTIFOLIA LEAF (UNII: FS7G8S6PJ8)		
HEMP (UNII: TD1MUT01Q7)		
DEHYDRATED ALCOHOL (UNII: 3K9958V90M)		
GREEN TEA LEAF (UNII: W2ZU1RY8B0)		
WATER (UNII: 059QF0KO0R)		
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)		
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)		
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)		
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)		
CHAMOMILE (UNII: FGL3685T2X)		
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)		

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
		NDC:73240- 903-01	89 g in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/30/2022	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	03/30/2022	

Labeler - Sunflora Inc. (067153368)

Establishment				
Name	Address	ID/FEI	Business Operations	
Inspec Solutions LLC.		081030372	manufacture(73240-903)	

Revised: 3/2022 Sunflora Inc.