NUTRASTATE SOOTHING RELIEF TOPICAL GEL- menthol gel
NUTRASTATE, 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.

Active ingredient

Active ingredient Purpose

Menthol 4%.....Topical Analgesic

Uses

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

UsesTemporary relief from minor aches and pains of muscle aches and pains of muscles and joints associated with arthritis, simple backache, strains and sprains

Warnings

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For external use only.

Flammable: Do not use while smoking or near heat or flame.

When using this product

When using this product ● avoid contact with the eyes or mucous membranes ● do not apply to wounds or damaged skin ● do not apply to the irritate skin ● do not bandage ● wash hands after use with cool water ● do not use with heating pad or device

Stop use and ask a doctor if

Stop use and ask a doctor if ● condition worsens, or it symptoms persist for more than 7 days, or clear up and occur again within a few days.

Keep out of reach of children

Keep out of reach of children. If accidentally ingested get medical help or contact a Poison Control Center immediately.

Directions **● Adults and children 2 years of age and older:**

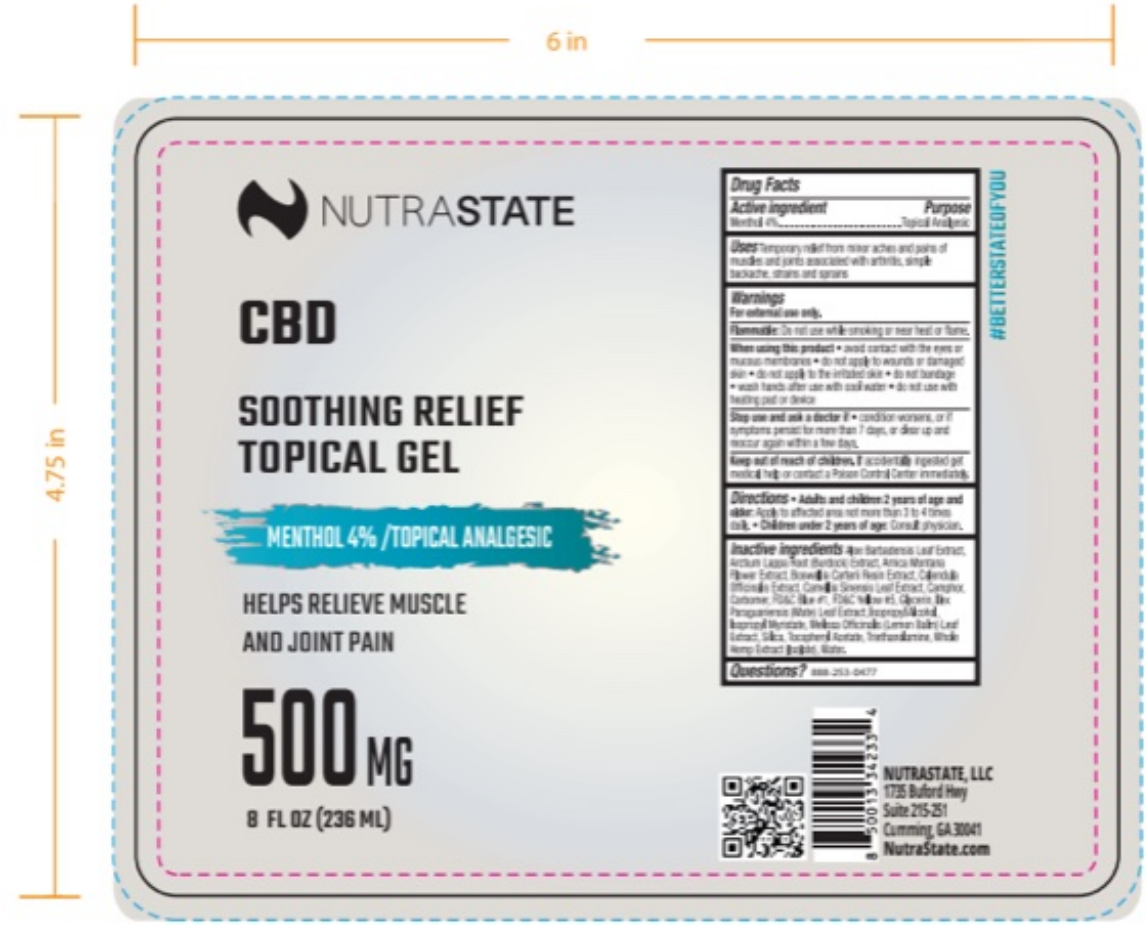
Apply to affected area not more than 3 to 4 times daily. ● **Children under 2 years of age:** Consult a physician.

Inactive ingredients

Inactive ingredients Aloe Barbadensis Leaf Extract, Arctium Lappa Root (Burdock) Extract, Arnica Montana Flower Extract, Boswellia Carterii ResinExtract, Calendula Officinalis Extract, Camellia Sinensis Leaf Extract, Camphor Carbomer, FD&C Blue #1, FD&C Yellow #5, Glycerin, Ilex Paraguariensis (Mate) Leaf Extract, Isopropyl Alcohol, Isopropyl Myristate, Melissa Officinalis (Lemon Balm) Leaf Extract, Silica, Tocopheryl Acetate, Triethanolamine, Whole Hemp Extract (Isolate), Water.

Questions?

Questions? 888-253-0477



NUTRASTATE SOOTHING RELIEF TOPICAL GEL

menthol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:81178-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	4 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
FRANKINCENSE (UNII: R9XLF1R1WM)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ARCTIUM LAPPA ROOT (UNII: 597E9BI3Z3)	
TROLAMINE (UNII: 9O3K93S3TK)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
WATER (UNII: 059QF0KO0R)	
HEMP (UNII: TD1MUT01Q7)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
CAMPHOR, (-)- (UNII: 213N3S8275)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
MELISSA OFFICINALIS LEAF (UNII: 50D2ZE9219)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81178-002-08	393 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	11/23/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	11/23/2020	

Labeler - NUTRASTATE, LLC (114472928)

Establishment

Name	Address	ID/FEI	Business Operations
InSpec Solutions, LLC		081030372	manufacture(81178-002)