## MYDERM COOLING MENTHOL PAIN RELIEF WITH 50 PERCENT MORE MENTHOL- menthol gel Inspec Solutions 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.

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#### myDerm Cooling Menthol Pain Relief Gel with 50% More Menthol

Active ingredient

Menthol 4%

Menthol 4% ...... Topical analgesic

Uses Temporary relief of pain

For external use only

DO not use in large quantities over raw surfaces and blistered area

When using this product

Use only as directed, read and follow all directions and warnings on this label, rare cases of serious burn have been reported with product of this type, do not bandage tightly or apply local heat (such as heating pads) to the area of use or use with medicated patch, avoid contact with eyes and mucous membranes

Stop use and ask doctor if, condition worsens, redness is present, irritation develops, 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.

#### **Directions**

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

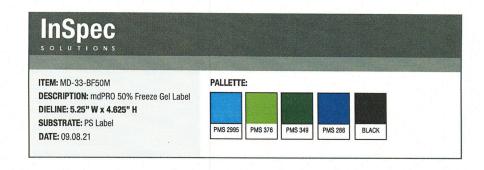
Silica

**Tocopheryl Acetate** 

Triethanolamine

Water





#### **MENTHOL**

menthol gel

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Prod	luct	Inform	ation

Product Type HUMAN OTC DRUG Item Code (Source) NDC:72667-021

**Route of Administration** TOPICAL

# Active Ingredient/Active Moiety Ingredient Name Basis of Strength MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) MENTHOL 6 g in 100 mL

Inactive Ingredients	
Ingredient Name	Strength
ISOPROPYL MYRISTATE (UNII: ORE8K4LNJS)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
FD&C YELLOW NO. 5 (UNII: 1753WB2F1M)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ARCTIUM LAPPA ROOT (UNII: 597E9BI3Z3)	
CAMPHOR (NATURAL) (UNII: N20HL7Q941)	
MELISSA OFFICINALIS LEAF (UNII: 50D2ZE9219)	
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
WATER (UNII: 059QF0KO0R)	
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
TROLAMINE (UNII: 903K93S3TK)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
FRANKINCENSE (UNII: R9XLF1R1WM)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GLYCERIN (UNII: PDC6A3C0OX)	

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
		NDC:72667- 021-01	89 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/27/2021	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part348	12/27/2021		

### Labeler - Inspec Solutions LLC. (081030372)

Establishment				
Name	Address	ID/FEI	Business Operations	
Inspec Solutions LLC.		081030372	manufacture(72667-021)	

Revised: 1/2023 Inspec Solutions LLC.