

**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



**Drug Facts**

Active ingredient	Purpose
Menthol 6%.....	Topical Analgesic

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

**Warnings**  
For external use only.  
**Flammable:** Do not use while smoking or near heat or flame.  
**When using this product** • avoid contacts with the eyes or mucous membranes • do not apply to wounds or damaged skin • do not apply to irritated skin • do not bandage • wash hands after use with cool water • do not use with heating pad or device.  
**Stop use and ask doctor if** • condition worsens, or if symptoms persist for more than 7 days, or clear up and reoccur again within a few days.  
**Keep out of reach of children.** If swallowed, 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 physician.

**Inactive ingredients** Aloe Barbardensis Leaf Extract, Arctium Lappa Root (Burdock) Extract, Amica Montana Flower Extract, Boswellia Carterii Resin Extract, 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, Water.

**Questions?** 1-855-MYDERM1


 Distributed by: myDerm  
 Daytona Beach, FL 32117  
 1-855-MYDERM1  
[www.shopmyderm.com](http://www.shopmyderm.com)








- Trim Line
- - - - - Text Safe Line
- - - - - Bleed Line

**InSpec**  
SOLUTIONS

**ITEM:** MD-33-BF50M  
**DESCRIPTION:** mdPRO 50% Freeze Gel Label  
**DIELINE:** 5.25" W x 4.625" H  
**SUBSTRATE:** PS Label  
**DATE:** 09.08.21

**PALLETTE:**

				
PMS 2995	PMS 376	PMS 349	PMS 286	BLACK

**MYDERM COOLING MENTHOL PAIN RELIEF WITH 50 PERCENT MORE**

# MENTHOL

menthol gel

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:72667-021
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>MENTHOL</b> (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	6 g in 100 mL

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>ISOPROPYL MYRISTATE</b> (UNII: 0RE8K4LNJS)	
<b>CALENDULA OFFICINALIS FLOWER</b> (UNII: P0M7O4Y7YD)	
<b>FD&amp;C YELLOW NO. 5</b> (UNII: I753WB2F1M)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>ARCTIUM LAPPAL ROOT</b> (UNII: 597E9BI3Z3)	
<b>CAMPHOR (NATURAL)</b> (UNII: N20HL7Q941)	
<b>MELISSA OFFICINALIS LEAF</b> (UNII: 50D2ZE9219)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>GREEN TEA LEAF</b> (UNII: W2ZU1RY8B0)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>ILEX PARAGUARIENSIS LEAF</b> (UNII: 1Q953B4O4F)	
<b>ISOPROPYL ALCOHOL</b> (UNII: ND2M416302)	
<b>CARBOMER 940</b> (UNII: 4Q93RCW27E)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	
<b>ARNICA MONTANA FLOWER</b> (UNII: OZ0E5Y15PZ)	
<b>FRANKINCENSE</b> (UNII: R9XLF1R1WM)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	

## Packaging

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

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
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.