MYDERM COOLING MENTHOL PAIN RELIEF ROLL-ON 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 Roll-On 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

Trim Line

Text Safe Line

Bleed Line

InSpec
SOLUTIONS

ITEM: MD-33-ROLB5
DESCRIPTION: mdPRO 50% Freeze Roll Label
DIELINE: 4.75" W x 3.00" H
SUBSTRATE: PS Label
DATE: 09.08.21

PALLETTE:

PMS 2995	PMS 376	PMS 349	PMS 286	BLACK

MYDERM COOLING MENTHOL PAIN RELIEF ROLL-ON WITH 50

PERCENT MORE MENTHOL

menthol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:72667-022
Route of Administration	TOPICAL		

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

Inactive Ingredients	
Ingredient Name	**Strength**
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ARCTIUM LAPPA ROOT (UNII: 597E9BI3Z3)	
CAMPHOR (NATURAL) (UNII: N20HL7Q941)	
MELISSA OFFICINALIS LEAF (UNII: 50D2ZE9219)	
.ALPHA.-TOCOPHEROL 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: 9O3K93S3TK)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
FRANKINCENSE (UNII: R9XLF1R1WM)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:72667-022-01	74 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(72667-022)

Revised: 1/2023 Inspec Solutions LLC.