BIOFREEZE ROLL-ON- menthol gel
REMEDYREPACK 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.

Biofreeze Roll-On

Drug Facts

Active Ingredients

Menthol USP 4%

Purpose

Cooling Pain Relief

Uses:

Temporary relief from minor aches and pains of sore muscles and joints associated with: - arthritis, - backache, - strains, - sprains

Warnings:

For external use only

Flammable: Keep away from excessive heat or open flame

Ask a doctor before use if you have:

Sensitive skin

When using this product:

- Avoid contact with eyes or mucous membranes
- Do not apply to wounds or damaged skin.
- Do not use with other ointments, creams, sprays, or liniments.
- Do not apply to irritated skin or if excessive skin irritation develops.
- Do not bandage
- Wash hands after use with cool water
- Do not use with heating pad or device.
- Store in a cool dry place

Stop use and ask a doctor if:

Condition worsens, or if symptoms persist for more than 7 days, or clear up and recur

If pregnant or breast-feeding:

Ask a health professional before use

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: Rub a thin film over affected areas not more than 4 times daily; massage not necessary
Children under 2 years of age: Consult physician

Inactive Ingredients:

Aloe Barbadensis Leaf Extract, Arnica Montana Flower Extract, Arctium Lappa Root (Burdock) Extract, Boswellia Carteril Resin Extract, Calendula Officinallis Extract, Carbomer, Camellia Sinensis (Green Tea) Leaf Extract, Camphor USP, Glycerin, Ilex Paraguariensis Leaf Extract, Isopropyl Alcohol, Ispropyl Myristate, Melissa Officinalis (Lemon Balm) Leaf Extract, Silicon Dioxide, Tocopheryl (Vitamin E) Acetate, Triethanolamine, Purified Water USP, Blue 1, Yellow 5

Questions or Comments

1-800-246-3733

Repackaged and Distributed By:

Remedy Repack, Inc.

625 Kolter Dr. Suite #4 Indiana, PA 1-724-465-8762

DRUG: Biofreeze Roll-On

GENERIC: MENTHOL

DOSAGE: GEL

ADMINSTRATION: TOPICAL

NDC: 70518-0485-0

PACKAGING: 74 mL in 1 BOTTLE

ACTIVE INGREDIENT(S):
- MENTHOL 40mg in 1mL

INACTIVE INGREDIENT(S):
- ALOE VERA LEAF
- ARNICA MONTANA FLOWER
- FRANKINCENSE
- CALENDULA OFFICINALIS FLOWER
- GREEN TEA LEAF
- GLYCERIN
- ILEX PARAGUARIENSIS LEAF
- ISOPROPYL ALCOHOL
- ISOPROPYL MYRISTATE
- MELISSA OFFICINALIS LEAF
- SILICON DIOXIDE
- .ALPHA.-TOCOPHEROL ACETATE
- TROLAMINE
- WATER
- FD&C BLUE NO. 1
- FD&C YELLOW NO. 5

Biofreeze Roll-On

Menthol 4%

40mg/1 mL Topical Gel

QTY: 74

ID #: .

NDC #: 70518-0485-00

LOT #:

MFG: Performance Health, Akron, OH 44310

NOT FOR RETAIL SALE

Expires:

Shape: .

Ref #: 59316-0205-14

Directions For Use: See Package Insert

Store at 20-25°C (68-77°F); excursions permitted to 15-30°C (59-86°F) [See USP]

Repackaged by:
RemedyRepack Inc., Indiana, PA 15701, 1-724-465-8762

BIOFREEZE ROLL-ON

menthol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70518-0485(NDC:59316-205)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	40 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
FRANKINCENSE (UNII: R9XLF1R1WM)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
GLYCERIN (UNII: PDC6A3C0OX)	
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)	

ISOPROPYL ALCOHOL (UNII: ND2M416302)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
MELISSA OFFICINALIS LEAF (UNII: 50D2ZE9219)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70518-0485-0	74 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/05/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	05/05/2017	

Labeler - REMEDYREPACK INC. (829572556)

Revised: 5/2020 REMEDYREPACK INC.