BIOFREEZE OVERNIGHT GEL- menthol gel
RB Health (US) 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.

Biofreeze Overnight Gel

Warnings

For external use only

Flammable: Keep away from excessive heat or open flame

When using this product:

• Use only as directed • Avoid contact with the eyes or on mucous membranes • Do not apply to wounds or damaged skin • Do not apply to irritated skin or if excessive irritation develops • Do not bandage tightly or use with heating pad or device •Children 2 years to under 12 years of age:Use only under adult supervision

Stop use and ask a doctor if:

You experience pain, swelling or blistering of the skin; condition worsens, or if symptoms persist for more than 7 days, or clear up and occur again within a few days; arthritic pain persists for more than 10 days, or redness is present, or in conditions affecting children under 12 years of age

If pregnant or breastfeeding:

Ask a health professional before use

Keep out of reach of children:

If swallowed, get medical help or contact a Poison Control Center right away

Directions

Directions

¢ adults and children 2 years of age and older: rub a thin film over affected area not more than 3 to 4 times daily

¢ children under 2 years of age: consult a physician

¢ wash hands after use with cool water

Other Info

Other information

¢ store at 20-25°C (68-77°F)

¢ store in a cool dry place away from direct sunlight

Inactive Ingredients

Inactive ingredients

Alcohol, Aloe Barbadensis Leaf Extract, Arctium Lappa Root Extract, Arnica Montana Flower Extract, Boswellia Carterii Resin Extract, Calendula Officinalis Leaf Extract, Camellia Sinensis Leaf Extract, Carbomer Interpolymer, Fragrance, Glycerin, Ilex Paraguariensis Leaf Extract, Isopropyl Alcohol, Melissa Officinalis Leaf Extract, Purified Water, Tocopherol Acetate, Trolamine

Questions or comments? 1-800-246-3733

Drug Facts

Dist. by: RB Health (US)
Parsippany, NJ 07054-0224

Uses

Uses

Temporarily relieves minor aches and pains of muscles and joints associated with:

¢ simple backache ¢ arthritis ¢ strains ¢ bruises ¢ sprains

Active

Active ingredient

Menthol 4% Purpose-Pain Relieving Gel

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Temporarily relieves minor aches and pains of muscles and joints associated with:

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NDC 59316-121-10

BiOFREEZE®

GEL

MENTHOL-PAIN
RELIEVING GEL

3 FL OZ 89 mL

BIOFREEZE OVERNIGHT GEL

menthol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:59316-121
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)	
ARCTIUM LAPPA ROOT (UNII: 597E9BI3Z3)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
MELISSA OFFICINALIS LEAF (UNII: 50D2ZE9219)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)	
WATER (UNII: 059QF0KO0R)	
TROLAMINE (UNII: 9O3K93S3TK)	
FRANKINCENSE (UNII: R9XLF1R1WM)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
ALCOHOL (UNII: 3K9958V90M)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59316-121-10	89 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/01/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	03/01/2023	

Labeler - RB Health (US) LLC (081049410)

Revised: 2/2023 RB Health (US) LLC