BIOFREEZE- menthol cream
RB Health (US) LLC

Biofreeze Overnight Relief Cream

Drug Facts

Active Ingredients:

Menthol USP 10%

Purpose

Cooling Pain Relief

Uses:

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

Warnings:

For external use only

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

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 breastfeeding:

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 12 years of age and older**: rub a thin film over affected area

not more
than 3 to 4 times daily
■ **children under 12 years of age:** consult a physician

■ wash hands after use with cool water

Inactive Ingredients:

Alcohol, Calcium Gluconate, Caprylic/Capric Triglyceride,
Caprylyl Glycol, Cetostearyl Alcohol, Dimethicone, Edetate Sodium, Fragrance,
Gluconolactone, Glycerin,
Glyceryl Stearate, Grapeseed Oil Refined, Hydroxyacetophenone, Ilex Paraguariensis Leaf Extract,
Iodopropynyl Butylcarbamate, Isopropyl Alcohol, PEG-4 Laurate, Phenoxyethanol, Polysorbate 60,
PurifiedWater, Sodium Benzoate, Sodium Hydroxide, Sodium Stearoyl Lactylate, Tocopheryl Acetate

Questions or Comments:

1-800-246-3733

Package Labeling:

BIOFREEZE
menthol cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:59316-870
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	100 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
PEG-4 LAURATE (UNII: AYF4VM3N1Z)	
GLYCERIN (UNII: PDC6A3C0OX)	
CALCIUM GLUCONATE (UNII: SQE6VB453K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
GLUCONOLACTONE (UNII: WQ29KQ9POT)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
HYDROXYACETOPHENONE (UNII: G1L3HT4CMH)	
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SODIUM STEAROYL LACTYLATE (UNII: IN99IT31LN)	
EDETATE SODIUM (UNII: MP1J8420LU)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
GRAPE SEED OIL (UNII: 930MLC8XGG)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59316-870-10	85 g in 1 JAR; Type 0: Not a Combination Product	02/15/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	02/15/2024	

Labeler - RB Health (US) LLC (081049410)