

BIOFREEZE FOOT- menthol cream
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 Foot Cream

Drug Facts

Active Ingredients:

Menthol 10%

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

Ask a doctor before use

if you have: Sensitive skin

When using this product:

• Avoid contact with the 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 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 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 areas not more than 4 times daily; massage not necessary
- **Children under 12 years of age:** Consult physician

Inactive Ingredients:

Caprylic/Capric Triglyceride, Cetearyl Alcohol, Diazolidinyl Urea, Dimethicone, Gluconolactone, Glycerin, Glyceryl Stearate, Ilex Paraguariensis Leaf Extract, Iodopropynyl Butylcarbamate, Polysorbate 60, Sodium Benzoate, Sodium Hydroxide, Sodium Stearoyl Lactylate, Tetrasodium EDTA, Tocopheryl Acetate, Vitis Vinifera (Grape) Seed Oil, Water

Questions or Comments:

1-800-246-3733

Package Labeling:



BIOFREEZE
COOL THE PAIN



FOOT CREAM

FAST ACTING
MENTHOL PAIN RELIEF

Net Wt. 4 oz / 113.3 grams

**COLD THERAPY PAIN RELIEF FOR SORE MUSCLES,
BACKACHES, SORE JOINTS AND ARTHRITIS**
LONG-LASTING • VANISHING SCENT • PARABEN-FREE

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For best results, use Biofreeze® in combination with care from a health professional. Find one in your area at Biofreeze.com.



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*Trusted by pharmacists, physical therapists, chiropractors, massage therapists, podiatrists and athletic trainers.

Manufactured in the U.S.A.
No Animal Testing
Does not contain NSAIDs,
Ibuprofen, Aspirin or Salicylate



NDC 59316-990-20
15031
P11133-R00

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BIOFREEZE FOOT

menthol cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59316-990
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
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
GLUCONOLACTONE (UNII: WQ29KQ9POT)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
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: 059QF0KOOR)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59316-990-20	113.3 g in 1 TUBE; Type 0: Not a Combination Product	01/27/2020	12/31/2024

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	01/27/2020	12/31/2024

Labeler - RB Health (US) LLC (081049410)