

BIOFREEZE FOOT CREAM- 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 ingredient

Menthol 10%

Purpose

Pain Relieving Cream

Uses

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

- simple backache
- arthritis
- strains
- bruises
- sprains

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

- 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

If pregnant or breast-feeding, 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

- 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

Other information

- store at 20-25°C (68-77°F)
- store in a cool dry place away from direct sunlight

Inactive ingredients

Caprylic/Capric Triglyceride, Caprylyl Glycol, Cetearyl Alcohol, Dimethicone, Gluconolactone, Glycerin, Glyceryl Stearate, Hydroxyacetophenone, Ilex Paraguariensis Leaf Extract, Iodopropynyl Butylcarbamate, Phenoxyethanol, 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

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

PRINCIPAL DISPLAY PANEL - 113.3 g Tube Label

CLINICALLY
RECOMMENDED*

NDC 59316-001-20

BiOFREEZE®
COOL THE PAIN

FOOT CREAM

MENTHOL-PAIN
RELIEVING CREAM

Net wt 4 OZ (113.3 g)



No Animal Testing
Does not contain NSAIDs,
Ibuprofen, Aspirin or Salicylate
www.biofreeze.com
15031 P11133-R02



NDC 59316-001-20

BIOFREEZE
COOL THE PAIN



FOOT CREAM
MENTHOL-PAIN
RELIEVING CREAM
Net wt 4 OZ (113.3 g)

Drug Facts

Active ingredient Menthol 10%.....**Purpose** Pain Relieving Cream

Uses Temporarily relieves minor aches and pains of muscles and joints associated with:
■ simple backache ■ arthritis ■ strains ■ bruises ■ sprains

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
■ 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

If pregnant or breast-feeding, 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
■ 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

Other information
■ store at 20-25°C (68-77°F)
■ store in a cool dry place away from direct sunlight

Inactive ingredients Caprylic/Capric Triglyceride, Caprylyl Glycol, Cetearyl Alcohol, Dimethicone, Gluconolactone, Glycerin, Glyceryl Stearate, Hydroxyacetophenone, Ilex Paraguariensis Leaf Extract, Iodopropynyl Butylcarbamate, Phenoxyethanol, 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

Dist. by: RB Health (US), Parsippany, NJ 07054-0224 ©2022 RB Health
*Based on a survey of Clinicians: chiropractors, podiatrists, massage therapists, physical therapists, retail pharmacists, and athletic trainers (IPSOS Clinician Survey).

1/4" NO PRINT AREA

BIOFREEZE FOOT CREAM

menthol cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59316-001
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)				
CAPRYLYL GLYCOL (UNII: 00YIU5438U)				
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)				
DIMETHICONE (UNII: 92RU3N3Y1O)				
GLUCONOLACTONE (UNII: WQ29KQ9POT)				
GLYCERIN (UNII: PDC6A3C0OX)				
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: 059QF0KOOR)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59316-001-10	85 g in 1 TUBE; Type 0: Not a Combination Product	03/12/2021	
2	NDC:59316-001-20	113.3 g in 1 TUBE; Type 0: Not a Combination Product	03/12/2021	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part348	03/12/2021		

Labeler - RB Health (US) LLC (081049410)