

BIOFREEZE FOAM- menthol liquid
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® Foam

Drug Facts

Active ingredient

Menthol 7%

Purpose

Pain Relieving Liquid

Uses

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

- simple backache
- arthritis
- strains
- bruises
- sprains

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

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 on to affected area not more than 3 to 4 times daily; massage not necessary
- 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

Alcohol Denat., Aloe Barbadensis Leaf Extract, Arctium Lappa Root Extract, Arnica Montana Flower Extract, Bis-PEG-10 Dimethicone, Boswellia Carterii Resin Extract, Calendula Officinalis Flower Extract, Camellia Sinensis Leaf Extract, Hydroxyethyl Cetyldimonium Phosphate, Ilex Paraguariensis Leaf Extract, Isopropyl Palmitate, Melissa Officinalis Leaf Extract, PEG-12 Dimethicone, Pentylene Glycol, PPG-24-Glycereth-24, Water

Questions or comments?

1-800-246-3733

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

PRINCIPAL DISPLAY PANEL - 88 mL Bottle Label

CLINICALLY
RECOMMENDED

NDC 59316-991-10

BIOFREEZE®
COOL THE PAIN

FAST
DRY
FOAM

MENTHOL-PAIN
RELIEVING LIQUID

- ⊕ RUBS IN EASILY
- ⊕ LIGHTWEIGHT FEEL
- ⊕ DRIES QUICKLY

3 FL OZ (88 mL)



BIOFREEZE
COOL THE PAIN

NDC 59316-991-10



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FAST DRY FOAM
MENTHOL-PAIN RELIEVING LIQUID

⊕ RUBS IN EASILY
⊕ LIGHTWEIGHT FEEL
⊕ DRIES QUICKLY

3 FL OZ (88 mL)

*Based on a survey of Clinicians: chiropractors, podiatrists, massage therapists, physical therapists, retail pharmacists, and athletic trainers (FPSOS Clinician Survey).

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Drug Facts

Active Ingredient *Purpose*
Menthol 7%.....Pain Relieving Liquid

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

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
 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

Directions ■ adults and children 12 years of age and older: rub a thin film on to affected area not more than 3 to 4 times daily; massage not necessary ■ 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 Alcohol Denat., Aloe Barbadosis Leaf Extract, Arctium Lappa Root Extract, Arnica Montana Flower Extract, Bis-PEG-10 Dimethicone, Boswellia Carnati Resin Extract, Calendula Officinalis Flower Extract, Camellia Sinenis Leaf Extract, Hydroxyethyl Cellulose, Isopropyl Palmitate, Malissa Officinalis Leaf Extract, PEG-12 Dimethicone, Polyethylene Glycol, PPG-24-Glycereth-24, Water

Questions or comments?
1-800-2-46-3733

BIOFREEZE FOAM

menthol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59316-991
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	70 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ARCTIUM LAPPA ROOT (UNII: 597E9BI3Z3)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
BIS-PEG-10 DIMETHICONE/DIMER DILINOLEATE COPOLYMER (UNII: CF5W1YCX11)	
FRANKINCENSE (UNII: R9XLF1R1WM)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
GREEN TEA LEAF (UNII: W2ZU1R98B0)	

HYDROXYETHYL CETYLDIMONIUM PHOSPHATE (UNII: 9G05UO431K)	
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B404F)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
MELISSA OFFICINALIS LEAF (UNII: 50D2ZE9219)	
PEG-12 DIMETHICONE (300 CST) (UNII: ZEL54N6W95)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
PPG-24-GLYCERETH-24 (UNII: V341SPY84U)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59316-991-10	88 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/27/2020	

Marketing Information

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

Labeler - RB Health (US) LLC (081049410)

Revised: 1/2022

RB Health (US) LLC