

BIOFREEZE ROLL-ON- 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® Roll-On

Drug Facts

Active ingredient

Menthol 4%

Purpose

Pain Relieving Gel

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, or in conditions affecting children under 12 years of age

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 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 information

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

Inactive ingredients

Aloe Barbadensis Leaf Extract, Arctium Lappa Root (Burdock) Extract, Arnica Montana Flower Extract, Blue 1, Boswellia Carterii Resin Extract, Calendula Officinalis Extract, Camellia Sinensis Leaf Extract, Camphor, Carbomer, Glycerin, Ilex Paraguariensis Leaf Extract, Isopropyl Alcohol, Isopropyl Myristate, Melissa Officinalis (Lemon Balm) Leaf Extract, Silica, Tocopheryl Acetate, Triethanolamine, Water, Yellow 5

Questions or comments?

1-800-246-3733

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

PRINCIPAL DISPLAY PANEL - 89 mL Bottle Carton

CLINICALLY
RECOMMENDED*

NDC 59316-205-10

BiOFREEZE®
COOL THE PAIN

ROLL-ON
MENTHOL-PAIN
RELIEVING GEL

3 FL OZ (89 mL)

SHAKE WELL
BEFORE EACH USE

NDC 59316-205-10

SHAKE WELL
BEFORE EACH USE



BIOFREEZE®

COOL THE PAIN

ROLL-ON
MENTHOL-PAIN
RELIEVING GEL
3 FL OZ (89 mL)

Drug Facts

Active ingredient **Purpose**
Menthol 4%.....Pain Relieving Gel

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, or in conditions affecting children under 12 years of age

Drug Facts (continued)

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

Inactive ingredients

Aloe Barbadensis Leaf Extract, Arctium Lappa Root (Burdock) Extract, Arnica Montana Flower Extract, Blue 1, Boswellia Carterii Resin Extract, Calendula Officinalis Extract, Camellia Sinensis Leaf Extract, Camphor, Carbomer, Glycerin, Ilex Paraguariensis Leaf Extract, Isopropyl Alcohol, Isopropyl Myristate, Melissa Officinalis (Lemon Balm) Leaf Extract, Silica, Tocopheryl Acetate, Triethanolamine, Water, Yellow 5

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).

Does not contain NSAIDs, Ibuprofen, Aspirin or Salicylate • No Animal Testing 11806 P05132-R09



BIOFREEZE ROLL-ON

menthol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59316-205
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	40 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
FRANKINCENSE (UNII: R9XLF1R1WM)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
GLYCERIN (UNII: PDC6A3C0OX)	
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B404F)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
MELISSA OFFICINALIS LEAF (UNII: 50D2ZE9219)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59316-205-10	89 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/17/2013	
2	NDC:59316-205-14	74 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/17/2013	

3	NDC:59316-205-81	2 in 1 CARTON	02/22/2022	
3	NDC:59316-205-10	89 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	01/17/2013	

Labeler - RB Health (US) LLC (081049410)

Revised: 2/2022

RB Health (US) LLC