

**BIOFREEZE OVERNIGHT 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 ® Overnight Roll-on**

**Drug Facts**

**Active**

Mentol USP 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 ■ children 2 years to under 12 years of age: use only under adult supervision

**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**

Alcohol, Aloe Barbadensis Leaf Extract, Arctium Lappa Root Extract, Arnica Montana Flower Extract, Boswellia Carterii Resin Extract, Calendula Officinalis Leaf Extract, Camellia Sinensis Leaf Extract, Carbomer Interpolymer, Colloidal Silicon Dioxide, Fragrance, Glycerin, Ilex Paraguariensis Leaf Extract, Isopropyl Alcohol, Melissa Officinalis Leaf Extract, Purified Water, Tocopherol Acetate, Trolamine

**Questions or Comments**

1-800-246-3733

**SPL UNCLASSIFIED SECTION**

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

**Principal Display Panel - 74 mL Bottle Label**

CLINICALLY RECOMMENDED

NDC 59316-207-14

BIOFREEZE

COOL THE PAIN

ROLL-ON

MENTHOL- PAIN RELIEVING GEL

2.5 FL OZ (74mL)

SHAKE WELL BEFORE EACH USE

**CLINICALLY APPROVED**

NDC 59316-207-14

SHAKE WELL BEFORE EACH USE

7 31124 44415 8

**BIOFREEZE**  
COOL THE PAIN

**OVERNIGHT RELIEF ROLL-ON MENTHOL-PAIN RELIEVING GEL**

LAVENDER SCENT  
2.5 FL OZ (74 mL)

<p><b>Drug Facts</b></p> <p><b>Active ingredient</b>      <b>Purpose</b> Menthol 4%.....Pain Relieving Gel</p> <p><b>Uses</b> Temporarily relieves minor aches and pains of muscles and joints associated with:  <ul style="list-style-type: none"> <li>■ simple backache   ■ arthritis   ■ strains</li> <li>■ bruises   ■ sprains</li> </ul> </p> <p><b>Warnings</b> For external use only. Flammable: Keep away from excessive heat or open flame</p> <p>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   ■ children 2 years to under 12 years of age: use only under adult supervision</p> <p>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</p>	<p><b>Drug Facts (continued)</b></p> <p>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.</p> <p><b>Directions</b>   ■ adults and children 2 years of age and older: rub a thin film over affected area not more than 3 to 4 times daily  <ul style="list-style-type: none"> <li>■ children under 2 years of age: consult a physician</li> <li>■ wash hands after use with cool water</li> </ul> </p> <p><b>Other information</b>   ■ store at 20-25°C (68-77°F)   ■ store in a cool dry place away from direct sunlight</p> <p><b>Inactive ingredients</b> Alcohol, Aloe Barbadosis Leaf Extract, Arctium Lappa Root Extract, Amica Montana Flower Extract, Boswellia Carterii Resin Extract, Calendula Officinalis Leaf Extract, Camellia Sinensis Leaf Extract, Carbomer Interpolymer, Colloidal Silicon Dioxide, Fragrance, Glycerin, Ilex Paraguariensis Leaf Extract, Isopropyl Alcohol, Melissa Officinalis Leaf Extract, Purified Water, Tocopherol Acetate, Trolamine</p> <p><b>Questions or comments?</b> 1-800-246-3733</p>
--	--

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   3251874   101422

**BIOFREEZE OVERNIGHT ROLL-ON**

menthol gel

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:59316-207
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	40 mg in 1 mL

**Inactive Ingredients**

Ingredient Name	Strength
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
GLYCERIN (UNII: PDC6A3C0OX)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
FRANKINCENSE (UNII: R9XLF1R1WM)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
MELISSA OFFICINALIS LEAF (UNII: 50D2ZE9219)	
ALCOHOL (UNII: 3K9958V90M)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ARCTIUM LAPPA ROOT (UNII: 597E9BI3Z3)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
WATER (UNII: 059QF0KO0R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B404F)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TROLAMINE (UNII: 9O3K93S3TK)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59316-207-14	74 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/16/2023	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	03/16/2023	

**Labeler** - RB Health (US) LLC (081049410)

Revised: 3/2023

RB Health (US) LLC