BIOFREEZE PROFESSIONAL- menthol, unspecified form spray 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® Professional Spray

Drug Facts

Active ingredient

Menthol 10.5%

Purpose

Pain Relieving Spray

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

Contents under pressure. Do not puncture or incinerate.

Do not store at temperature above 120°F.

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: spray 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., Arnica Montana Flower Extract, Calendula Officinalis Flower Extract, Camellia Sinensis Leaf Extract, Chamomilla Recutita (Matricaria) Flower Extract, Dimethyl Sulfone (MSM), Echinacea Angustifolia Extract, Ilex Paraguariensis Leaf Extract, Isopropyl Myristate, Juniperus Communis Fruit Extract, Water

Questions or comments?

1-800-246-3733

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

PRINCIPAL DISPLAY PANEL - 118 mL Bottle Label

CLINICALLY RECOMMENDED*

NDC 59316-120-20

BiOFREEZE® PROFESSIONAL

SPRAY MENTHOL-PAIN RELIEVING SPRAY

4 FL OZ (118 mL)

360° SPRAY

PRESS DOWN FIRMLY TO ACTIVATE SPRAYER FOR FIRST USE

To not store at temperature above 120°F.

ontents under pressure. Do not puncture or incinerate. lammable: Keep away from excessive heat or open flame

When using this product

Stop use and ask a doctor if

you experience pain, swelling or blistering of the skin

arthritic pain persists for more than 10 days, or condition worsens, or if symptoms persist for more than days or clear up and occur again within a few days

use only as directed

avoid confact 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

Officinalis Rower Extract, Carnellia Sinensis Leaf Extract Charnomilla Recutita (Matricaria) Flower Extract, Dimeth

(MSM), Echinacea Angustiolia Extract, llex

188

Isopropy I Myristate, Juniperus

Questions or comments? 1-800-246-3733 Communis Fruit Extract, Water



NDC 59316-120-20

SPRAY

MENTHOL-PAIN RELIEVING SPRAY

4 FL OZ (118 mL)

Drug Facts

Active ingredieni Wenthol 10.5% Uses

oints associated with: arthritis strains emporarity relieves minor aches and pains of muscles and simple backache
bruises
spra ■ sprains

Warnings For external use only.

Pain Relieving Purpose

Directions

If pregnant or breast-feeding, ask a health professional Drug Facts Keep out of reach of children. help or contact a Poison Control If swallowed, get medica Center right

(continued

adults and children 12 years of ag on to affected area not more than massage not necessary of age and older: s han 3 to 4 times daily

children under 12 years of age: consult a physician
 wash hands after use with cool water

store at 20-25°C (68-77°F) store in a cool dry place away Other information Alcohol Denat., Amica Montana Flower Extract, Calendula Inactive ingredients

ω

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

TOPICAL

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

No Animal Testing • Does not contain NSAIDs, Ibuprofen, Aspirin or Salicylate

www.biofreeze.com DOT SP 15792 M5655 13422 P07885-R11



BIOFREEZE PROFESSIONAL

menthol, unspecified form spray

Product Information

Route of Administration

Product Type HUMAN OTC DRUG Item Code (Source) NDC:59316-120

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	105 mg in 1 mL

Inactive Ingredients			
Ingredient Name	Strength		
ALCOHOL (UNII: 3K9958V90M)			
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)			
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)			
GREEN TEA LEAF (UNII: W2ZU1RY8B0)			
CHAMOMILE (UNII: FGL3685T2X)			
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)			
ECHINACEA ANGUSTIFOLIA WHOLE (UNII: VB06AV5US8)			
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)			
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)			
JUNIPER BERRY (UNII: O84B5194RL)			
WATER (UNII: 059QF0KO0R)			

F	Packaging						
#	tem Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:59316-120- 30	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/03/2016				
2	NDC:59316-120- 20	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/03/2016				

Marketing Information					
Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
part348	06/03/2016				
	Application Number or Monograph Citation	Application Number or Monograph Marketing Start Citation Date			

Labeler - RB Health (US) LLC (081049410)

Revised: 5/2022 RB Health (US) LLC