BIOFREEZE- menthol spray
RB Health (US) LLC
Reference Label Set Id: bceb0d38-bb4f-4048-bfea-06a508e06255

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

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 59316-114-25

BiOFREEZE®
COOL THE PAIN

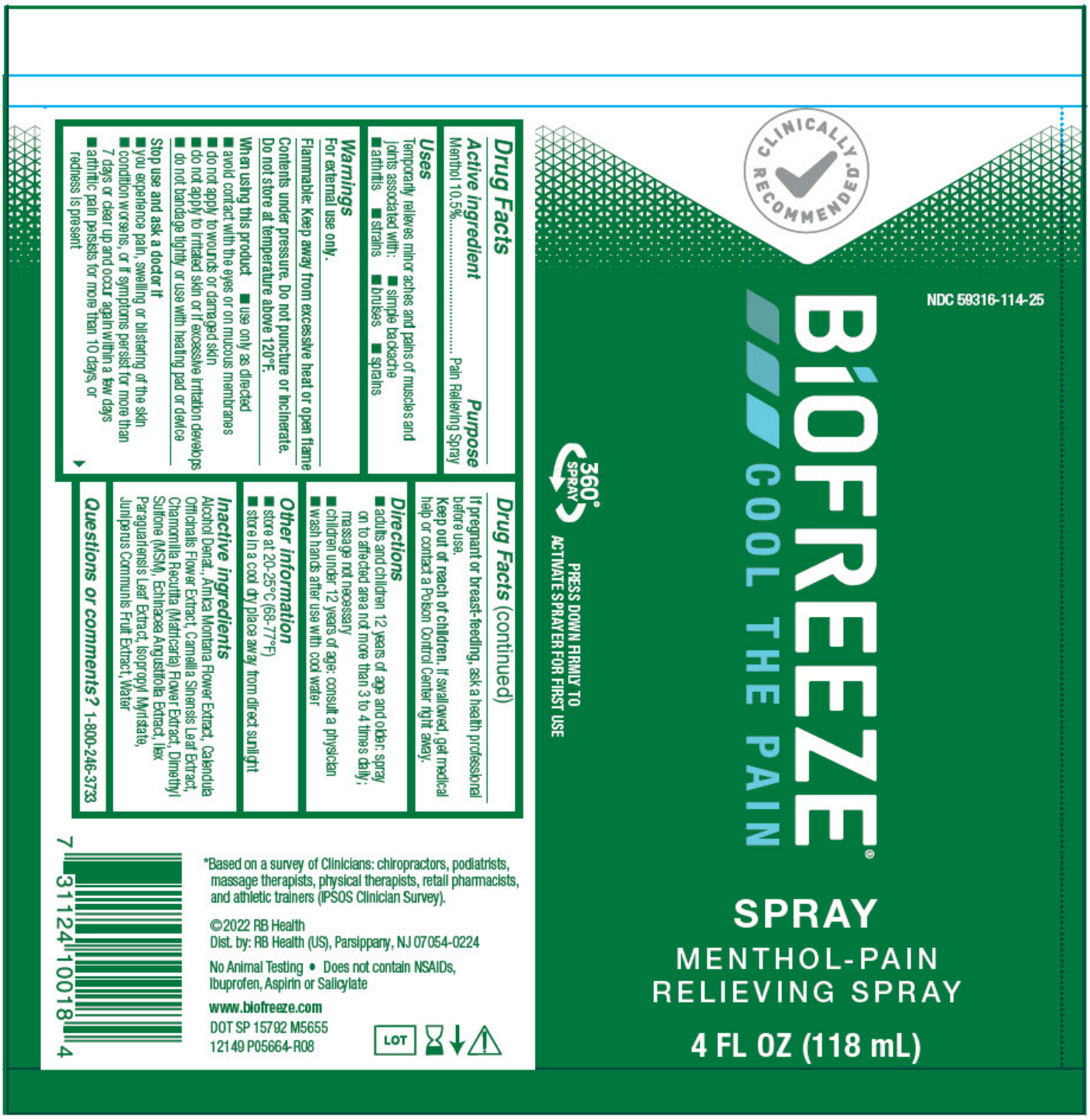
SPRAY

MENTHOL-PAIN
RELIEVING SPRAY

4 FL OZ (118 mL)

360°
SPRAY

PRESS DOWN FIRMLY TO
ACTIVATE SPRAYER FOR FIRST USE



BIOFREEZE

menthol spray

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:59316-114
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	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)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59316-114-50	10 in 1 BOX	02/19/2014	12/31/2021
1		1 mL in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:59316-114-25	118 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	02/19/2014	
3	NDC:59316-114-30	473 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	02/19/2014	
4	NDC:59316-114-10	89 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/19/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	02/19/2014	

Labeler - RB Health (US) LLC (081049410)

Revised: 5/2022 RB Health (US) LLC