BIOFREEZE- menthol gel
Reckitt Benckiser LLC

BiOFREEZE ®

Drug Facts

Active Ingredients:

Menthol 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

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 breastfeeding:

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 - 473 mL Bottle Label

CLINICALLY
RECOMMENDED ®

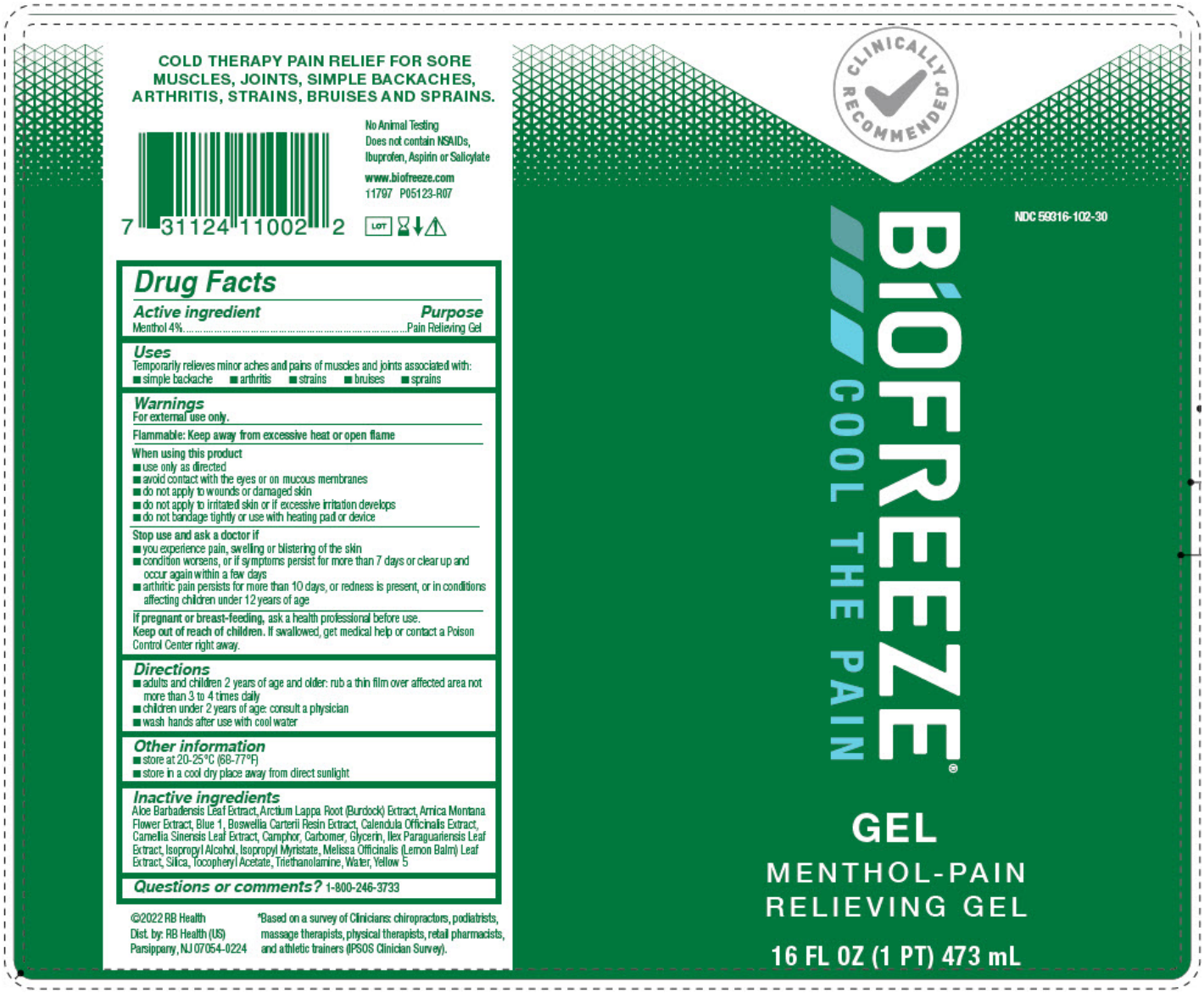
NDC 59316-102-30

BiOFREEZE ®
COOL THE PAIN

GEL

MENTHOL-PAIN
RELIEVING GEL

16 FL OZ (1 PT) 473 mL



BIOFREEZE

menthol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:59316-102
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**

.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
ARCTIUM LAPPA ROOT (UNII: 597E9BI3Z3)	
FRANKINCENSE (UNII: R9XLF1R1WM)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)	
GLYCERIN (UNII: PDC6A3C0OX)	
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
MELISSA OFFICINALIS LEAF (UNII: 50D2ZE9219)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
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:59316-102-10	5 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2012	
2	NDC:59316-102-11	3 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2012	
3	NDC:59316-102-15	89 mL in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product	01/03/2012	12/31/2018
4	NDC:59316-102-20	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2012	
5	NDC:59316-102-25	118 mL in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product	01/03/2012	12/31/2021
6	NDC:59316-102-30	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2012	
7	NDC:59316-102-40	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2012	
8	NDC:59316-102-50	3785 mL in 1 CONTAINER; Type 0: Not a Combination Product	01/03/2012	
9	NDC:59316-102-98	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2012	
10	NDC:59316-102-80	44 mL in 1 TUBE; Type 0: Not a Combination Product	11/02/2018	
11	NDC:59316-102-12	89 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/19/2016	
12	NDC:59316-102-16	89 mL in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product	09/19/2016	12/31/2019
13	NDC:59316-102-28	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/19/2016	
14	NDC:59316-102-90	100 in 1 CARTON	01/03/2012	
14	NDC:59316-102-10	5 mL in 1 BOTTLE; Type 0: Not a Combination Product		
15	NDC:59316-102-91	10 in 1 CARTON	01/03/2012	12/31/2025

15	NDC:59316-102-11	3 mL in 1 BOTTLE; Type 0: Not a Combination Product		
16	NDC:59316-102-92	16 in 1 CARTON	01/03/2012	12/31/2025
16	NDC:59316-102-11	3 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 Drug	M017	01/03/2012	

Labeler - Reckitt Benckiser LLC (094405024)

Revised: 5/2026 Reckitt Benckiser LLC