BIOFREEZE MENTHOL- menthol, unspecified form patch
RB Health (US) LLC

Biofreeze ®
Menthol Patches

Drug Facts

Active ingredient

Menthol 5%

Purpose

Pain Relieving Patch

Uses

Temporarily relieves minor aches and pains of muscles and joints associated with:
- simple backache
- arthritis
- strains
- bruises
- sprains

Warnings

For external use only.

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: Clean and dry affected area, pop apart and partially peel back protective film and apply exposed patch to site of pain. Carefully remove remaining film while pressing the patch to skin and leave in place for up to 8 hours. Use on affected area not more than 3 to 4 times daily.
- 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

1,2-Hexanediol, Aloe Barbadensis Leaf Extract, Arnica Montana Flower Extract,

Boswellia Carterii Resin Extract, Camellia Sinensis Leaf Extract, Carboxymethylcellulose Sodium, Dihydroxyaluminum Aminoacetate, Ethylhexylglycerin, Glycerin, Iodopropynyl Butylcarbamate, Kaolin, Mineral Oil, Petrolatum, Phenoxyethanol, Polyacrylic Acid, Polysorbate 80, Povidone, Propylene Glycol, Purified Water, Sodium Polyacrylate, Tartaric Acid, Titanium Dioxide

Questions or comments?

1-866-682-4639

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

PRINCIPAL DISPLAY PANEL - 12 Patch Pouch Carton

CLINICALLY
RECOMMENDED*

NDC 59316-992-08

BiOFREEZE ®
COOL THE PAIN

LARGE
PATCHES

MENTHOL-PAIN
RELIEVING PATCH

Designed to provide up to
8 hours of long lasting pain relief

Proven cold therapy formula for sore
muscles, simple backaches, and joint pain

Flexible fabric for superior performance and comfort

12 LARGE PATCHES

5.5 in x 3.94 in (14 cm x 10 cm) each

BIOFREEZE MENTHOL

menthol, unspecified form patch

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:59316-992
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	0.05 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
FRANKINCENSE (UNII: R9XLF1R1WM)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	

CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)	
DIHYDROXYALUMINUM AMINOACETATE (UNII: DO250MG0W6)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLYCERIN (UNII: PDC6A3C0OX)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
KAOLIN (UNII: 24H4NWX5CO)	
MINERAL OIL (UNII: T5L8T28FGP)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PETROLATUM (UNII: 4T6H12BN9U)	
POLYACRYLIC ACID (450000 MW) (UNII: KD3S7H73D3)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JNI2J)	
TARTARIC ACID (UNII: W4888I119H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color		**Score**	
Shape	RECTANGLE	**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59316-992-07	1 in 1 POUCH	03/04/2022	
1		9 g in 1 PATCH; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
2	NDC:59316-992-08	12 in 1 CARTON	03/04/2022	
2		9 g in 1 PATCH; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
3	NDC:59316-992-09	5 in 1 CARTON	03/04/2022	
3		9 g in 1 PATCH; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
4	NDC:59316-992-36	12 in 1 CARTON	03/04/2022	
4		1 in 1 POUCH		
4		9 g in 1 PATCH; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
5	NDC:59316-992-32	1 in 1 POUCH	03/04/2022	
5		20 g in 1 PATCH; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
6	NDC:59316-992-33	1 in 1 POUCH	03/04/2022	

6		13 g in 1 PATCH; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
7	NDC:59316-992-04	4 in 1 CARTON	09/07/2024	
7		20 g in 1 PATCH; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
8	NDC:59316-992-34	15 in 1 CARTON	10/01/2024	
8		9 g in 1 PATCH; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	03/04/2022	

Labeler - RB Health (US) LLC (081049410)

Revised: 4/2024 RB Health (US) LLC