

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

Biofreeze[®] Overnight Relief Patch

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° (68-77°F)
- store in a cool dry place away from direct sunlight

Inactive ingredients

Benzalkonium Chloride, Carboxymethylcellulose Sodium, Dihydroxyaluminum Aminoacetate, Edetate Disodium, Glycerin, Kaolin, Lauralkonium Chloride, Lavender Oil, Mineral Oil, Petrolatum, 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

Made in China

PRINCIPAL DISPLAY PANEL - 4 Patch Pouch Carton

CLINICALLY
RECOMMENDED

NDC 59316-005-04

BIOFREEZE[®]
COOL THE PAIN

OVERNIGHT
RELIEF
PATCHES

MENTHOL-TOPICAL
ANALGESIC

Overnight pain relief patch
Scented with lavender
essential oil

Designed to stay on
through the night



BIOFREEZE OVERNIGHT RELIEF

menthol, unspecified form patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59316-005
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	0.3 g in 6 g

Inactive Ingredients

Ingredient Name	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)	
DIHYDROXYALUMINUM AMINOACETATE (UNII: DO250MG0W6)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
KAOLIN (UNII: 24H4NWX5CO)	
LAURALKONIUM CHLORIDE (UNII: 07HUP5A29X)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	

MINERAL OIL (UNII: T5L8T28FGP)	
PETROLATUM (UNII: 4T6H12BN9U)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
TARTARIC ACID (UNII: W4888I119H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0K00R)	
POLYACRYLIC ACID (450000 MW) (UNII: KD3S7H73D3)	
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JN12J)	

Product Characteristics

Color		Score	
Shape	RECTANGLE	Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59316-005-03	6 g in 1 PATCH; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)	02/01/2022	
2	NDC:59316-005-04	4 in 1 CARTON	02/01/2022	
2		6 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	02/01/2022	

Labeler - RB Health (US) LLC (081049410)

Revised: 12/2023

RB Health (US) LLC