

**BIOFREEZE MENTHOL- menthol, unspecified form
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?

1-800-246-3733

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

PRINCIPAL DISPLAY PANEL - Kit Carton

CLINICALLY
RECOMMENDED*

NDC 59316-887-04

BiOFREEZE[®]
COOL THE PAIN

EXTRA 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

4 PATCHES | 2 SIZES
EXTRA LARGE
AND LONG

2 EXTRA LARGE 9.84 in x 5.5 in (25 cm x 14 cm) each
2 LONG 7.87 in x 3.94 in (20 cm x 10 cm) each

EXTRA LARGE PATCHES

BIOFREEZE
COOL THE PAIN

EXTRA LARGE PATCHES
MENTHOL-PAIN RELIEVING PATCH

4 PATCHES | 2 SIZES EXTRA LARGE AND LONG

2 EXTRA LARGE 9.84 in x 5.5 in (25 cm x 14 cm) each
2 LONG 7.87 in x 3.94 in (20 cm x 10 cm) each

Drug Facts
Active ingredient: Menthol 5%, Purpose: Pain Relieving Patch
Uses: Temporarily relieves minor aches and pains of muscles and joints associated with: ■ simple backaches ■ 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 ■ symptoms last 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 an 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, Amica Montana Flower Extract, Boswellia Carteri Resin Extract, Camelia Sinensis Leaf Extract, Carbonicdihydroxyketone Sodium, ChondroitinSulfate, ChondroitinSulfate, Glycolic Acid, Hydroxypropyl Butylcarbamate, Kaolin, Mineral Oil, Petrolatum, Phenylethylamine, Polysorbate Acid, Polyethylene Glycol, Propylene Glycol, Purified Water, Sodium Polycrylate, Tartaric Acid, Titanium Dioxide
Questions or comments? 1-866-682-4639

PATCH USAGE INSTRUCTIONS

- 1 Clean and dry affected area
- 2 Pop apart and peel back
- 3 Remove film and apply exposed patch to site of pain

SEE BACK PANEL FOR DETAILED DIRECTIONS

BIOFREEZE MENTHOL
menthol, unspecified form kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59316-887
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59316-887-04	1 in 1 KIT	03/10/2022	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 PATCH	20 g
Part 2	1 PATCH	13 g

Part 1 of 2

BIOFREEZE MENTHOL

menthol, unspecified form patch

Product Information

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: 05I15JN12J)	
TARTARIC ACID (UNII: W4888I119H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	

Product Characteristics

Color		Score	
Shape	RECTANGLE	Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59316-992-32	1 in 1 POUCH		
1		20 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	03/10/2022	

Part 2 of 2

BIOFREEZE MENTHOL

menthol, unspecified form patch

Product Information

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
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
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)	
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:59316-992-33	1 in 1 POUCH		
1		13 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	03/10/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	03/10/2022	

Labeler - RB Health (US) LLC (081049410)