

**BIOFREEZE DAY AND OVERNIGHT- menthol
RB Health (US) LLC**

Biofreeze Day & Overnight Patches

Drug Facts

Menthol 5%

Pain Relieving Patch

Uses

Temporarily relieves minor aches and pains of muscles and joints associated with:

- simple backache
- arthritis
- strains
- bruises
- sprains

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

Large Patch:

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

Overnight Relief Patch:

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

1-866-682-4639

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Menthol 5%

Purpose:

Pain Relieving Patch



BIOFREEZE[®]

COOL THE PAIN

DAY & OVERNIGHT PATCHES



NDC 58316-832-94

BIOFREEZE[®]

COOL THE PAIN

DAY & OVERNIGHT PATCHES

MENTHOL-PAIN RELIEVING PATCH

BIOFREEZE[®]
COOL THE PAIN
DAY & OVERNIGHT
PATCHES

BIOFREEZE[®]
COOL THE PAIN

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

USE ONLY AS DIRECTED.
Refer to Drug Facts directions for each patch. Do not exceed 3 to 4 patches to the affected area daily.

6X LARGE PATCHES

☒ Proven cold therapy formula for sore muscles, joints, simple backaches, arthritis, strains, bruises, and sprains

🕒 Designed to provide up to 8 hours of relief

3X OVERNIGHT RELIEF PATCHES

🌸 Overnight pain relief patch scented with lavender essential oil

🕒 Comfortable flexible fabric and stays in place overnight

9 PATCHES | 2 SIZES

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

3 OVERNIGHT RELIEF 5.125 in x 2.6 in (13 cm x 6.6 cm) each



LARGE 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°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

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°C (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

*Based on a survey of Clinicians: chiropractors, podiatrists, massage therapists, physical therapists, retail pharmacists, and athletic trainers (PSOS Clinician Survey).

**PAIN RELIEF PATCHES
FOR SORE MUSCLES,
JOINTS, SIMPLE
BACKACHES, ARTHRITIS,
STRAINS, BRUISES,
AND SPRAINS.**

**DAY & OVERNIGHT
PATCHES**

©2023 RB Health
Dist. by: RB Health (US)
Parsippany, NJ 07054-0224
Made in China

No Animal Testing

Does not contain NSAIDs,
Ibuprofen, Aspirin or Salicylate

www.biofreeze.com 040523

3268235



BIOFREEZE DAY AND OVERNIGHT

menthol kit

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:59316-832

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59316-832-94	1 in 1 KIT	05/31/2023	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	3 PATCH	18 g in 3
Part 2	6 PATCH	54 g in 6

Part 1 of 2

BIOFREEZE OVERNIGHT RELIEF

menthol, unspecified form patch

Product Information

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
LAURALKONIUM CHLORIDE (UNII: 07HUP5A29X)	
TARTARIC ACID (UNII: W4888I119H)	
POLYACRYLIC ACID (450000 MW) (UNII: KD3S7H73D3)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
MINERAL OIL (UNII: T5L8T28FGP)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
KAOLIN (UNII: 24H4NWX5CO)	
DIHYDROXYALUMINUM AMINOACETATE (UNII: DO250MG0W6)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
PETROLATUM (UNII: 4T6H12BN9U)	

SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JN12J)	
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:59316-005-03	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	05/22/2023	

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
WATER (UNII: 059QF0KO0R)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
PHENOXYETHANOL (UNII: H1E492ZZ3T)	
PETROLATUM (UNII: 4T6H12BN9U)	

GLYCERIN (UNII: PDC6A3C0OX)
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)
MINERAL OIL (UNII: T5L8T28FGP)
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)
GREEN TEA LEAF (UNII: W2ZU1RY8B0)
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)
KAOLIN (UNII: 24H4NWX5CO)
FRANKINCENSE (UNII: R9XLF1R1WM)
DIHYDROXYALUMINUM AMINOACETATE (UNII: DO250MG0W6)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
TARTARIC ACID (UNII: W4888I119H)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JN12J)
POLYACRYLIC ACID (450000 MW) (UNII: KD3S7H73D3)
POLYSORBATE 80 (UNII: 6OZP39ZG8H)

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		
1		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	05/22/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	05/22/2023	

Labeler - RB Health (US) LLC (081049410)

Revised: 4/2024

RB Health (US) LLC