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

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

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, DihydroxyaluminumAminoacetate, Ethylhexylglycerin, Glycerin, Iodopropynyl Butylcarbamate, Kaolin, Mineral Oil, Petrolatum, Phenoxyethanol, Polyacrylic Acid, Polysorbate 80, Povidone, Propylene Glycol, PurifiedWater, 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

CLINICALLY RECOMMENDED

NDC 59316-832-94

BIOFREEZE®
COOL THE PAIN
DAY & OVERNIGHT PATCHES

BIOFREEZE®
COOL THE PAIN

DAY & OVERNIGHT PATCHES

MENTHOL-PAIN RELIEVING PATCH

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

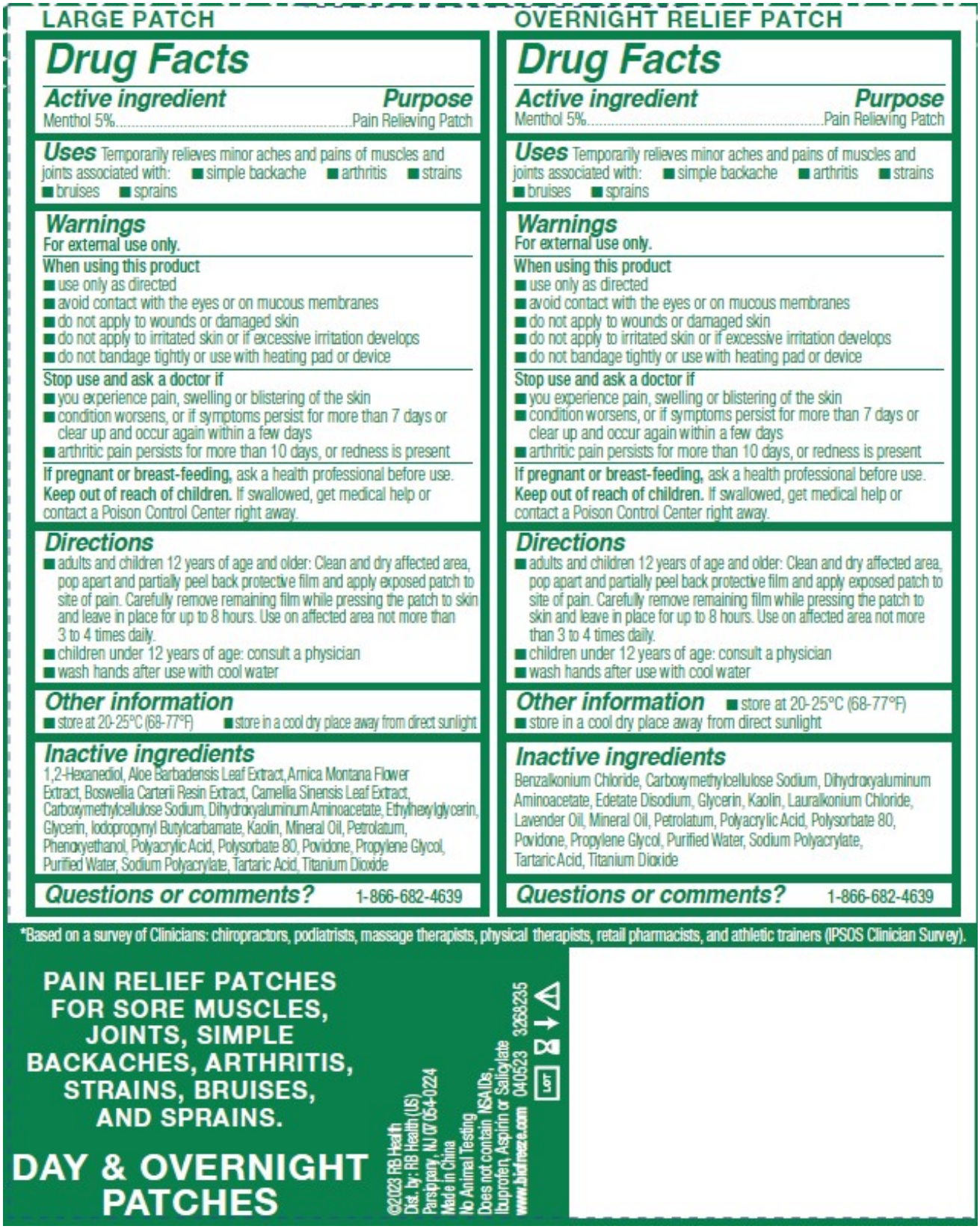
6 LARGE 5.5 in x 3.94 in (14 cm x 10 cm) each
3 OVERNIGHT RELIEF 5.125 in x 2.6 in (13 cm x 6.6 cm) each

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.



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: 05I15JNI2J)	
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 not final	part348	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: HIE492ZZ3T)	
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: 05I15JNI2J)	
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 not final	part348	05/22/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	05/22/2023	

Labeler - RB Health (US) LLC (081049410)

Revised: 5/2023 RB Health (US) LLC