

**BIOFREEZE MENTHOL- menthol, unspecified form  
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®  
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**

Aloe Barbadosis Leaf Extract, Arnica Montana Flower Extract, Boswellia Carterii Resin Extract, Camellia Sinensis Leaf Extract, Cellulose Gum, Dihydroxyaluminum Aminoacetate, Ethylhexylglycerin, Glycerin, Iodopropynyl Butylcarbamate, Kaolin, Mineral Oil, Phenoxyethanol, Petrolatum, Polyacrylic Acid, Polysorbate 80, Propylene Glycol, PVP, Sodium Polyacrylate, Tartaric Acid, Titanium Dioxide, Water

### **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



**BIOFREEZE**  
COOL THE PAIN

**EXTRA LARGE PATCHES**



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

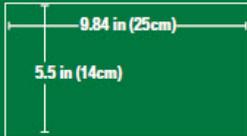
2 EXTRA LARGE 9.84 in x 5.5 in (25 cm x 14 cm) each  
2 LONG 7.87 in x 3.94 in (20 cm x 10 cm) each

**PATCH USAGE  
INSTRUCTIONS**

- 1**  
Remove patch from outer package
- 2**  
Pop apart and peel back one side of film
- 3**  
Place on affected area
- 4**  
Remove remaining film while pressing patch to skin

SEE BACK PANEL FOR DETAILED DIRECTIONS





NOT ACTUAL SIZE

### 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

Aloe Barbadosensis Leaf Extract, Arnica Montana Flower Extract, Boswellia Carterii Resin Extract, Camellia Sinensis Leaf Extract, Cellulose Gum, Dihydroxyaluminum Aminoacetate, Ethylhexylglycerin, Glycerin, Isopropylmyristate, Kaolin, Mineral Oil, Phenoxethanol, Petrolatum, Polyacrylic Acid, Polysorbate 80, Propylene Glycol, PVP, Sodium Polyacrylate, Tartaric Acid, Titanium Dioxide, Water

Questions or comments? 1-800-246-3733

## EXTRA LARGE PATCHES

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



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

©2022 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  
15000 P11066-R03



**BIOFREEZE**  
COOL THE PAIN

EXTRA  
LARGE  
PATCHES

7 3112400277 8





## BIOFREEZE MENTHOL

menthol, unspecified form kit

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:59316-887
---------------------	----------------	---------------------------	---------------

### 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

<b>Item Code (Source)</b>	NDC:59316-992
---------------------------	---------------

<b>Route of Administration</b>	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)	

<b>Carboxymethylcellulose sodium, unspecified</b> (UNII: K679OBS311)
<b>DIHYDROXYALUMINUM AMINOACETATE</b> (UNII: DO250MG0W6)
<b>Ethylhexylglycerin</b> (UNII: 147D247K3P)
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)
<b>IODOPROPYNYL BUTYLCARBAMATE</b> (UNII: 603P14DHEB)
<b>KAOLIN</b> (UNII: 24H4NWX5CO)
<b>Mineral Oil</b> (UNII: T5L8T28FGP)
<b>Phenoxyethanol</b> (UNII: HIE492ZZ3T)
<b>Petrolatum</b> (UNII: 4T6H12BN9U)
<b>POLYACRYLIC ACID (450000 MW)</b> (UNII: KD3S7H73D3)
<b>Polysorbate 80</b> (UNII: 6OZP39ZG8H)
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)
<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)
<b>SODIUM POLYACRYLATE (2500000 MW)</b> (UNII: 05I15JN12J)
<b>TARTARIC ACID</b> (UNII: W4888I119H)
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)
<b>WATER</b> (UNII: 059QF0K00R)

### Product Characteristics

<b>Color</b>		<b>Score</b>	
<b>Shape</b>	RECTANGLE	<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### 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 not final	part348	03/10/2022	

### Part 2 of 2

## BIOFREEZE MENTHOL

menthol, unspecified form patch

### Product Information

<b>Item Code (Source)</b>	NDC:59316-992
<b>Route of Administration</b>	TOPICAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>MENTHOL, UNSPECIFIED FORM</b> (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	0.05 g in 1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>ARNICA MONTANA FLOWER</b> (UNII: OZ0E5Y15PZ)	
<b>FRANKINCENSE</b> (UNII: R9XLF1R1WM)	
<b>GREEN TEA LEAF</b> (UNII: W2ZU1RY8B0)	
<b>Carboxymethylcellulose sodium, unspecified</b> (UNII: K679OBS311)	
<b>DIHYDROXYALUMINUM AMINOACETATE</b> (UNII: DO250MG0W6)	
<b>Ethylhexylglycerin</b> (UNII: 147D247K3P)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>IODOPROPYNYL BUTYLCARBAMATE</b> (UNII: 603P14DHEB)	
<b>KAOLIN</b> (UNII: 24H4NWX5CO)	
<b>Mineral Oil</b> (UNII: T5L8T28FGP)	
<b>Phenoxyethanol</b> (UNII: HIE492ZZ3T)	
<b>Petrolatum</b> (UNII: 4T6H12BN9U)	
<b>POLYACRYLIC ACID (450000 MW)</b> (UNII: KD3S7H73D3)	
<b>Polysorbate 80</b> (UNII: 6OZP39ZG8H)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)	
<b>SODIUM POLYACRYLATE (2500000 MW)</b> (UNII: 05I15JN12J)	
<b>TARTARIC ACID</b> (UNII: W4888I119H)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>WATER</b> (UNII: 059QF0KO0R)	

### Product Characteristics

<b>Color</b>		<b>Score</b>	
<b>Shape</b>	RECTANGLE	<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### 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 not final	part348	03/10/2022	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	03/10/2022	

**Labeler** - RB Health (US) LLC (081049410)

Revised: 9/2022

RB Health (US) LLC