

**BIOFREEZE FLEXIBLE RELIEF STRIP- menthol patch**  
**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.*

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**Biofreeze® Flexible Relief Strip**

**Drug Facts**

**Active ingredient**

Menthol 5.6%

**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.
- do not stretch the patch during application as it should be comfortable and not tight
- do not overwrap or wrap patches over themselves
- for best adhesion: area should be clean, dry, and smooth
- 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 Barbadensis Leaf Extract, Arnica Montana Flower Extract, Benzalkonium Chloride, Boswellia Carterii Resin Extract, Camellia Sinensis Leaf Extract, Carboxymethylcellulose Sodium, Dihydroxyaluminum Aminoacetate, Edetate Disodium, Glycerin, Isopropyl Myristate, Kaolin, L-Tartaric Acid, Lauralkonium Chloride, Mineral Oil, Nonoxynol-10, Petrolatum, Polyacrylic Acid, Polysorbate 80, Propylene Glycol, PVP, Sodium Polyacrylate, Titanium Dioxide, Water

### **Questions or comments?**

**1-800-246-3733**

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

### **PRINCIPAL DISPLAY PANEL - 4 Strip Carton**

CLINICALLY  
RECOMMENDED\*

NDC 59316-004-04

BiOFREEZE®  
COOL THE PAIN

FLEXIBLE  
RELIEF  
STRIPS  
MENTHOL-PAIN  
RELIEVING PATCH

Designed to provide up to  
8 hours of long lasting  
pain relief

Strong adhesion to stay  
through any movement

Optimal thickness for  
comfort and flexibility

4 STRIPS |  
EXTRA  
LONG

10 in x 2 in  
(25.4 cm x 5 cm) each



NDC 59316-004-04

**BIOFREEZE**  
COOL THE PAIN  
**FLEXIBLE RELIEF STRIPS**

# BIOFREEZE<sup>®</sup>

COOL THE PAIN

## FLEXIBLE RELIEF STRIPS

MENTHOL-PAIN RELIEVING PATCH

- ⌚ Designed to provide up to **8 hours of long lasting pain relief**
- ⊕ **Strong adhesion** to stay through any movement
- ⊙ **Optimal thickness** for comfort and flexibility



### FLEXIBLE RELIEF STRIPS USAGE INSTRUCTIONS

- 1 Clean and dry affected area
- 2 Peel back protective film
- 3 Apply exposed strip to site of pain

**4 STRIPS** | EXTRA LONG

10 in x 2 in  
(25.4 cm x 5 cm) each

SEE BACK PANEL FOR DETAILED DIRECTIONS

Glue

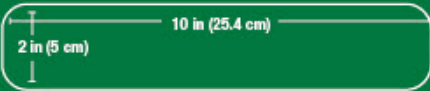
Glue

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# BIOFREEZE

COOL THE PAIN

FLEXIBLE RELIEF STRIPS



NOT ACTUAL SIZE

## Drug Facts

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**Uses**  
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 ■ 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**  
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 ■ do not stretch the patch during application as it should be comfortable and not tight  
 ■ do not overlap or wrap patches over themselves  
 ■ for best adhesion: area should be clean, dry, and smooth  
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**Questions or comments?** 1-800-246-3733

## FLEXIBLE RELIEF STRIPS

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 (IPSO's Clinician Survey).

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 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  
 15181 P11543-R01



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# BIOFREEZE FLEXIBLE RELIEF STRIP

menthol patch

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:59316-004
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>MENTHOL, UNSPECIFIED FORM</b> (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	56 mg in 1 g

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>ARNICA MONTANA FLOWER</b> (UNII: OZ0E5Y15PZ)	
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7)	
<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>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>ISOPROPYL MYRISTATE</b> (UNII: ORE8K4LNJS)	
<b>KAOLIN</b> (UNII: 24H4NWX5CO)	
<b>TARTARIC ACID</b> (UNII: W4888I119H)	
<b>LAURALKONIUM CHLORIDE</b> (UNII: 07HUP5A29X)	
<b>MINERAL OIL</b> (UNII: T5L8T28FGP)	
<b>NONOXYNOL-10</b> (UNII: K7O76887AP)	
<b>PETROLATUM</b> (UNII: 4T6H12BN9U)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>WATER</b> (UNII: 059QF0KO0R)	

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:59316-004-01	1 in 1 POUCH	03/31/2021	
1		6 g in 1 PATCH; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

2	NDC:59510-004-04	4 in 1 CARTON	03/31/2021	
2		6 g in 1 PATCH; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>		<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph not final	part348		03/31/2021	

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

Revised: 1/2022

RB Health (US) LLC