

BIOFREEZE- 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.

Biofreeze

Drug Facts

Active Ingredients

Menthol 5%

Purpose

Cooling Pain Relief

Uses:

Temporary relief from minor aches and pains of sore muscles and joints associated with:
• arthritis • backache • strains • sprains

Warnings

For external use only

Ask a doctor before use if you have:

Sensitive skin

When using this product:

• Use only as directed • Do not bandage tightly or use with heating pad or device • Avoid contact with eyes or mucous membranes • Do not apply to wounds or damaged skin • Do not use with other ointments, creams, sprays, or liniments • Do not apply to irritated skin • Store in a cool dry place away from direct sunlight

Stop use and ask a doctor if:

burning discomfort or excessive skin irritation develops, condition worsens, or if symptoms persist for more than 7 days, or clear up and occur within a few days

If pregnant or breast-feeding:

Ask a health professional before use

Keep out of reach of children:

If accidentally ingested, get medical help or contact a Poison Control Center immediately

Directions

- **Adults and children 12 years of age and older:** clean and dry affected area, partially peel back protective film and apply exposed patch to site of pain. Carefully remove remaining film while pressing patch to skin and leave in place for up to 8 hours. Use on affected areas not more **than** 4 times daily. Wash hands with cool water after use.
- **Children under 12 years of age:** Consult physician

Inactive Ingredients

Aloe Barbadensis Leaf Extract, Arnica Montana Flower Extract, Boswellia Carterii Resin Extract, Camellia Sinensis Leaf Extract, Diazolidinyl Urea, Dihydroxyaluminum Aminoacetate, Glycerin, Iodopropynyl Butylcarbamate, Kaolin, Polyacrylic Acid, Polysorbate 80, Propylene Glycol, PVP, Sodium Polyacrylate, Tartaric Acid, Titanium Dioxide, Water

Questions or Comments:

1-800-246-3733

Package Labeling: 59316-993-07




PAIN RELIEF PATCHES FOR SORE MUSCLES, BACKACHES, SORE JOINTS AND ARTHRITIS	
LONG LASTING • VANISHING SCENT • PARABEN-FREE	
Drug Facts	
Active Ingredients: Menthol USP 5%	PurposeCooling Pain Relief
Uses: Temporary relief from minor aches and pains of sore muscles and joints associated with: • arthritis • backache • strains • sprains	
Warnings: For external use only Ask a doctor before use if you have: Sensitive skin	
When using this product: • Use only as directed • Do not bandage tightly or use with heating pad or device • Avoid contact with eyes or mucous membranes • Do not apply to wounds or damaged skin • Do not use with other ointments, creams, sprays, or liniments • Do not apply to irritated skin • Store in a cool dry place away from direct sunlight	
Stop use and ask a doctor if: Burning discomfort or excessive skin irritation develops, condition worsens, or if symptoms persist for more than 7 days, or clear up and recur	
If pregnant or breastfeeding: Ask a health professional before use	
Keep out of reach of children: If accidentally ingested, get medical help or contact a Poison Control Center immediately	
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 patch to skin and leave in place for up to 8 hours. Use on affected areas not more than 4 times daily. Wash hands with cool water after use • Children under 12 years of age: Consult physician	
Inactive Ingredients: Aloe Barbadensis Leaf Extract, Arnica Montana Flower Extract, Boswellia Carterii Resin Extract, Camellia Sinensis Leaf Extract, Diazolidinyl Urea, Dihydroxyaluminum Aminoacetate, Glycerin, Iodopropynyl Butylcarbamate, Kaolin, Polyacrylic Acid, Polysorbate 80, Propylene Glycol, PVP, Sodium Polyacrylate, Tartaric Acid, Titanium Dioxide, Water	
Questions or Comments: 1-800-246-3733	

*Trusted by pharmacists, physical therapists, chiropractors, massage therapists, podiatrists and athletic trainers.

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1245 Home Avenue, Akron, OH 44310
www.biofreeze.com

NDC 59316-993-07
14723-ART-R01
Not for individual resale



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Package Labeling: 59316-993-09



LARGE PATCHES


PAIN RELIEF PATCHES FOR SORE MUSCLES, BACKACHES, AND JOINT PAIN
LONG-LASTING • VANISHING SCENT • PARABEN-FREE

NOT ACTUAL SIZE

5.5" (14cm)

- Provides up to 8 hours of pain relief
- Proven cold therapy formula
- Flexible fabric stays in place
- Targeted, mess-free application

Drug Facts	Purpose
Active Ingredients: Menthol USP 5%	Cooling Pain Relief
Uses: Temporary relief from minor aches and pains of sore muscles and joints associated with • arthritis • backache • strains • sprains	
Warnings: For external use only Ask a doctor before use if you have: Sensitive skin	
When using this product: • Use only as directed • Do not bandage lightly or use with heating pad or device • Avoid contact with eyes or mucous membranes • Do not apply to wounds or damaged skin • Do not use with other ointments, creams, sprays, or liniments • Do not apply to irritated skin • Store in a cool dry place away from direct sunlight	
Stop use and ask a doctor if: Burning discomfort or excessive skin irritation develops, condition worsens, or if symptoms persist for more than 7 days, or clear up and recur	
If pregnant or breastfeeding: Ask a health professional before use	
Keep out of reach of children: If accidentally ingested, get medical help or contact a Poison Control Center immediately	
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 areas not more than 4 times daily. Wash hands with cool water after use. • Children under 12 years of age: Consult physician	
Inactive Ingredients: Aloe Barbadensis Leaf Extract, Arnica Montana Flower Extract, Boswellia Carterii Resin Extract, Camellia Sinensis Leaf Extract, Discolidinyl Urea, Dihydroxyaluminum Aminoacetate, Glycothim, Iodopropynyl Butylcarbamate, Kaolin, Polyacrylic Acid, Polysoorbate 80, Propylene Glycol, PVP, Sodium Polyacrylate, Tartaric Acid, Titanium Dioxide, Water	
Questions or Comments: 1-800-246-3733	



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Made in China
Does not contain NSAIDs,
Ibuprofen, Aspirin or Salicylate
P10468-906
14672



LARGE PATCHES

CLINICALLY RECOMMENDED

#1



LARGE PATCHES
FAST ACTING MENTHOL PAIN RELIEF

➊ Remove patch from outer package

➋ Pop apart and peel back one side of film

➌ Place on affected area

➍ Remove remaining film while pressing patch to skin




- ➊ Designed to provide up to **8 hours of long lasting pain relief**
- ➋ Proven cold therapy formula for **sore muscles, backaches, and joint pain**
- ➌ **Flexible fabric** for superior performance and comfort

Contains five individually packaged pain relief patches
5 LARGE 5.5" x 3.94" (14cm x 10cm)

BIOFREEZE
COOL THE PAIN

LARGE PATCHES



6 17100 72118 2

Package Labeling: 59316-993-08



PAIN RELIEF PATCHES FOR SORE MUSCLES, BACKACHES, SORE JOINTS AND ARTHRITIS
LONG LASTING • VANISHING SCENT • PARABEN-FREE

- Provides up to 8 hours of pain relief
- Proven cold therapy formula
- Flexible fabric stays in place
- Targeted, mess-free application

LOT (LINE)
NOT ACTUAL SIZE
LOT (LINE)

Drug Facts

Active Ingredients: Menthol USP 5%.....	Purpose Cooling Pain Relief
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Uses:
Temporary relief from minor aches and pains of sore muscles and joints associated with: • arthritis • backache • strains • sprains

Warnings:
For external use only

Ask a doctor before use if you have: Sensitive skin

When using this product: • Use only as directed • Avoid contact with eyes or mucous membranes • Do not apply to wounds or damaged skin • Do not use with other ointments, creams, sprays, or liniments • Do not apply to irritated skin • Wash hands after use with cool water • Do not bandage or use with heating pad or device • Store in a cool dry place away from direct sunlight

Stop use and ask a doctor if: You experience pain, swelling or blistering; condition worsens, or if symptoms persist for more than 7 days, or clear up and occur again within a few days

If pregnant or breastfeeding: Ask a health professional before use

Keep out of reach of children: If accidentally ingested, get medical help or contact a Poison Control Center immediately

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 patch to skin and leave in place for up to 8 hours. Use on affected areas no more than 4 times daily. Wash hands with cool water after use
- Children under 12 years of age: Consult physician

Inactive ingredients: Aloe Barbadosis Leaf Extract, Amica Montana Flower Extract, Boswellia Carterii Resin Extract, Camellia Sinensis Leaf Extract, Diszolidinyl Urea, Dihydroxyaluminum Aminoacetate, Glycerin, Iodopropnyl Butylcarbamate, Kaolin, Polyacrylic Acid, Polysorbate 80, Propylene Glycol, PVP, Sodium Polycrylate, Tartaric Acid, Titanium Dioxide, Water

Questions or comments: 1-800-246-3733

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Made in China

Does not contain NSAIDs, Ibuprofen, Aspirin or Salicylate

P11562-900
15200

LOT



BIOFREEZE
COOL THE PAIN

LARGE PATCHES



BIOFREEZE
COOL THE PAIN

12x LARGE PATCHES
FAST ACTING MENTHOL PAIN RELIEF



- ⌚ Designed to provide up to **8 hours of long lasting pain relief**
- ⊗ Proven cold therapy formula for **sore muscles, backaches, and joint pain**
- ⊕ **Flexible fabric** for superior performance and comfort

Contains twelve individually packaged pain relief patches
12 LARGE 5.5" x 3.94" (14cm x 10cm)

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



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BIOFREEZE
COOL THE PAIN

1 LARGE PATCH
FAST ACTING MENTHOL PAIN RELIEF

1 PATCH - 5.5" x 3.94" (14cm x 10cm)

PAIN RELIEF PATCHES FOR SORE MUSCLES, BACKACHES, SORE JOINTS AND ARTHRITIS
LONG LASTING • VANISHING SCENT • PARABEN-FREE

Drug Facts

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Inactive ingredients: Aloe Barbadosis Leaf Extract, Amica Montana Flower Extract, Boswellia Carterii Resin Extract, Camellia Sinensis Leaf Extract, Diszolidinyl Urea, Dihydroxyaluminum Aminoacetate, Glycerin, Iodopropnyl Butylcarbamate, Kaolin, Polyacrylic Acid, Polysorbate 80, Propylene Glycol, PVP, Sodium Polycrylate, Tartaric Acid, Titanium Dioxide, Water

Questions or Comments: 1-800-246-3733

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NDC 59316-993-07
14723-ART-R03
Made in China



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BIOFREEZE

menthol patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59316-993
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)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
DIHYDROXYALUMINUM AMINOACETATE (UNII: DO250MG0W6)	
GLYCERIN (UNII: PDC6A3C0OX)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
KAOLIN (UNII: 24H4NWX5CO)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
TARTARIC ACID (UNII: W4888I119H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59316-993-07	1 in 1 POUCH	01/30/2019	12/31/2024
1		1 in 1 PACKET		
1		9 g in 1 PATCH; Type 0: Not a Combination Product		
2	NDC:59316-993-09	5 in 1 CARTON	01/30/2019	12/31/2024
2		1 in 1 POUCH		
2		9 g in 1 PATCH; Type 0: Not a Combination Product		
3	NDC:59316-993-08	12 in 1 CARTON	02/04/2021	12/31/2024
3		1 in 1 POUCH		
3		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	01/30/2019	12/31/2024

Labeler - RB Health (US) LLC (081049410)

Revised: 12/2021

RB Health (US) LLC