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 Patch

Drug Facts

Active Ingredients:

Menthol USP 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 • 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 not more than 4 times daily. Wash hands with cool water after use
• **Children under 12 years of age:** Consult physician

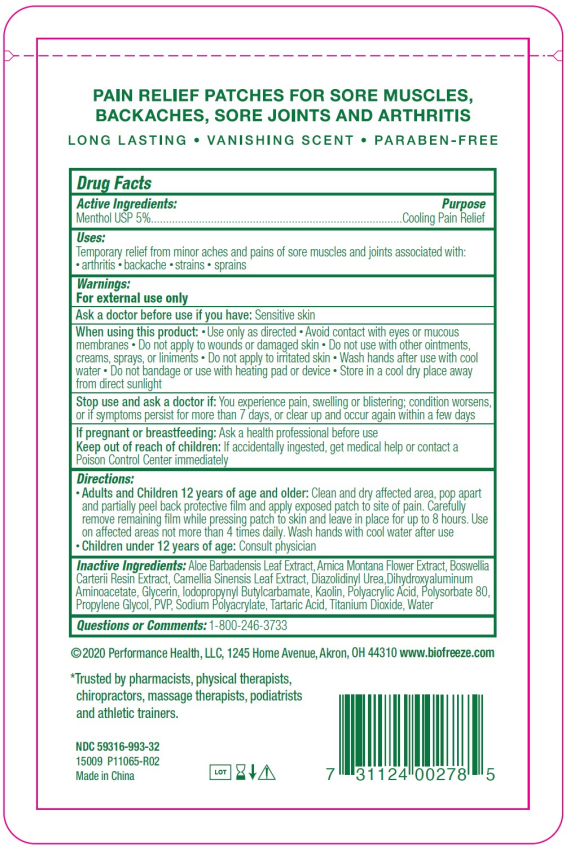
Inactive Ingredients:

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:59316-993-32



Package Labeling:59316-993-33

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**
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)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
FRANKINCENSE (UNII: R9XLF1R1WM)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
DIHYDROXYALUMINUM AMINOACETATE (UNII: DO250MG0W6)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59316-993-32	1 in 1 POUCH	01/30/2019	12/31/2024
1		20 g in 1 PATCH; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
2	NDC:59316-993-33	1 in 1 POUCH	01/30/2019	12/31/2024
2		13 g in 1 PATCH; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
3	NDC:59316-993-36	12 in 1 CARTON	01/30/2019	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