

BIOFREEZE- menthol patch
Performance Health, 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

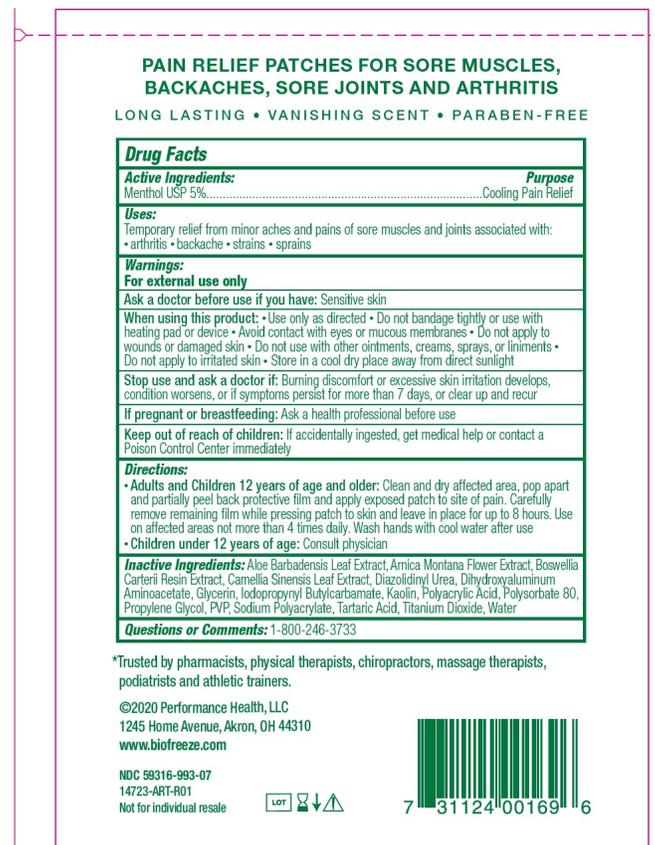
Inactive Ingredients

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

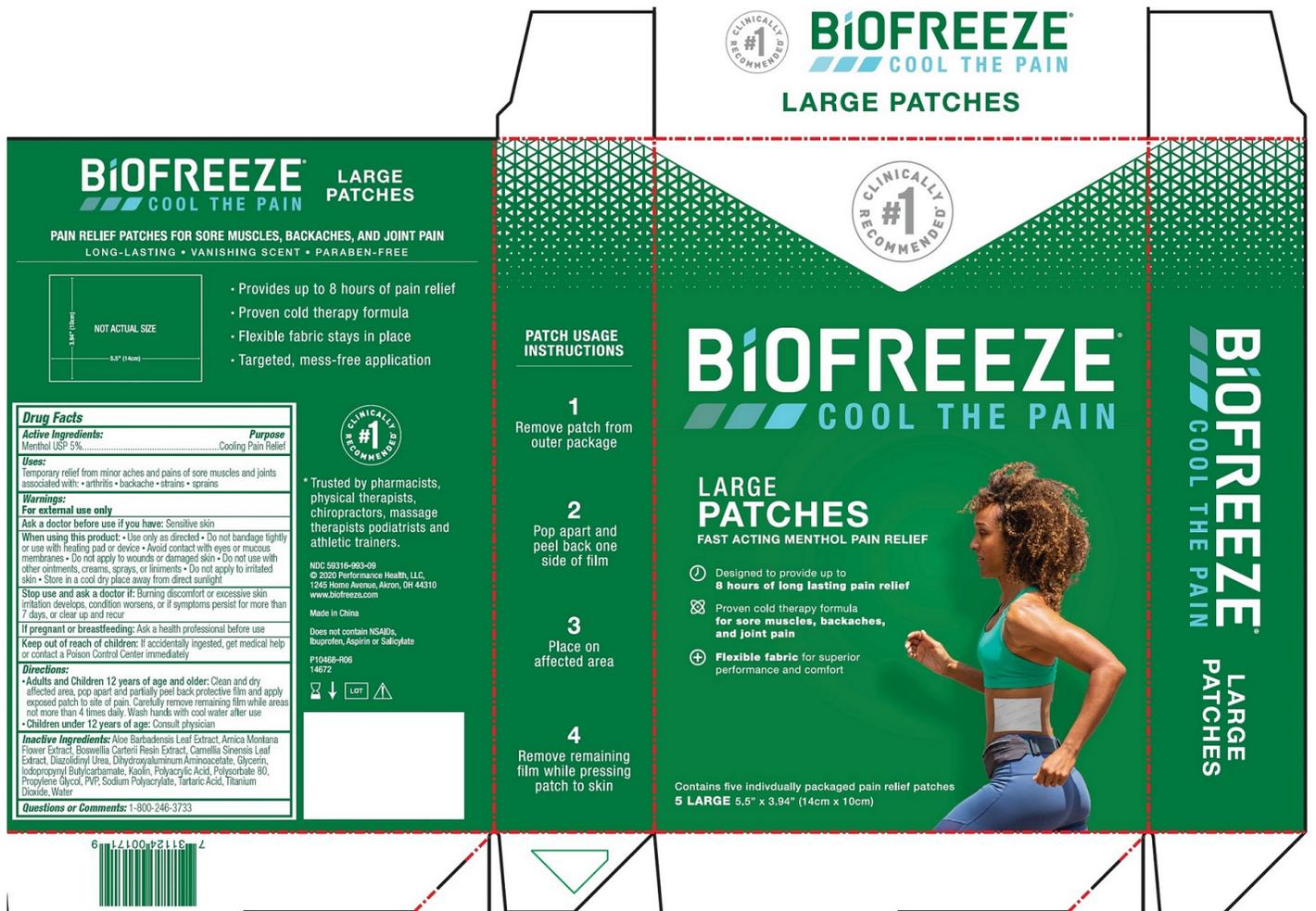
Questions or Comments :

1-800-246-3733

Package Labeling: 59316-993-07



Package Labeling: 59316-993-09



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 (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	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 AMINO ACETATE (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	
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	
2		1 in 1 POUCH		
2		9 g in 1 PATCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	01/30/2019	

Labeler - Performance Health, LLC (794324061)