

BIOTEMPER SPORTS- menthol spray
Scientific Solutions Global, 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.

BIOTEMPER

Drug Facts

Active Ingredient

Menthol 10%

Purpose

Topical Analgesic

Uses

For temporary relief of minor aches and pains of muscles and joints associated with • simple backache • arthritis • strains • bruises • sprains

Warnings

For external use only

Flammable keep away from fire or flame

When using this product • avoid contact with eyes or mucous membranes • do not bandage tightly • do not apply to wound or damaged or irritated skin

Stop use and consult a doctor if • condition worsens • symptoms persist for more than 7 days • clear up and occur again within a few days

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 2 years of age and older: Apply to affected area not more than 4 times daily • Children under 2 years of age, consult a physician • Massage not necessary • Shake well before use

Inactive Ingredients

Aloe Vera Oil, Arnica Flower Tincture, Boswellia Powder, Camphor, Frankincense Oil, Green Tea, Isopropyl Alcohol, Lavender Oil, Propylene Glycol, Tea Tree Oil, Thymol, Vitamin E

Other Information

• store in a cool and dry place with lid closed tightly

Questions or Comments?

Call us at: 1(516) 543-3376 M-F 9am-6pm EST or E-mail:info@biotemper.com

SPORTS SPRAY

FOR ARTHRITIS, SPRAINS, SORE MUSCLES, BRUISES, & BACK PAIN

COLD PAIN RELIEF THERAPY

MADE WITH HERBAL & HOMEOPATHIC INGREDIENTS

NO NSAIDs, IBUPROFEN, ASPIRIN, OR SALICYLATE

BIOTEMPER.COM

DISTRIBUTED BY:

SCIENTIFIC SOLUTIONS GLOBAL, LLC

CARLE PLACE, NY

PROUDLY MADE IN USA

Packaging

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COLD PAIN RELIEF THERAPY
MADE WITH HERBAL & HOMEOPATHIC INGREDIENTS
NO NSAIDs, IBUPROFEN, ASPIRIN, OR SALICYLATE

BIOTEMPER.COM
4 fl oz (118 mL)

BIOTEMPER SPORTS

menthol spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71718-444	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
	Ingredient Name	Basis of Strength	Strength	
	MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	10 g in 100 mL	
Inactive Ingredients				
	Ingredient Name	Strength		
	ALOE VERA LEAF (UNII: ZY81Z83H0X)			
	ARNICA MONTANA (UNII: O80TY208ZW)			
	FRANKINCENSE (UNII: R9XLF1R1WM)			
	CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)			
	FRANKINCENSE OIL (UNII: 67ZYA5T02K)			
	GREEN TEA LEAF (UNII: W2ZU1RY8B0)			
	ISOPROPYL ALCOHOL (UNII: ND2M416302)			
	LAVENDER OIL (UNII: ZBP1YXW0H8)			
	PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
	TEA TREE OIL (UNII: VIF565UC2G)			
	THYMOL (UNII: 3J50XA376E)			
	.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)			
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71718-444-01	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/01/2017	
2	NDC:71718-444-02	2 in 1 PACKAGE	09/01/2017	
2		118 mL in 1 BOTTLE; 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	09/01/2017		

Labeler - Scientific Solutions Global, LLC (097291290)

Establishment

Name	Address	ID/FEI	Business Operations
Scientific Solutions Global, LLC		097291290	manufacture(71718-444)