# 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.

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#### **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?**

#### 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** 

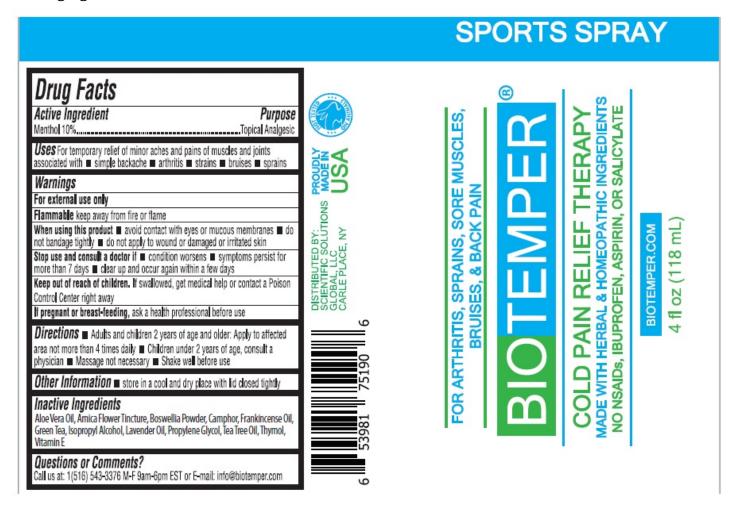
**DISTRIBUTED BY:** 

SCIENTIFIC SOLUTIONS GLOBAL, LLC

CARLE PLACE, NY

PROUDLY MADE IN USA

## **Packaging**



## **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: L7T10 EIP3A) (MENTHOL - UNII:L7T10 EIP3A)	MENTHOL, UNSPECIFIED FORM	10 g in 100 mL		

Inactive Ingredients		
Ingredient Name	Strength	
ALOE VERA LEAF (UNII: ZY81Z83H0X)		
ARNICA MONTANA (UNII: O80TY208ZW)		
FRANKINCENSE (UNII: R9 XLF1R1WM)		
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)		
FRANKINCENSE O IL (UNII: 67ZYA5T02K)		
GREEN TEA LEAF (UNII: W2ZU1RY8B0)		
ISOPROPYL ALCOHOL (UNII: ND2M416302)		
LAVENDER O IL (UNII: ZBP1YXW0H8)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
TEA TREE OIL (UNII: VIF565UC2G)		
THYMOL (UNII: 3J50 XA376E)		
.ALPHATO COPHEROL (UNII: H4N855PNZ1)		

]	Packaging				
#	t Item Code	Package Description	<b>Marketing Start Date</b>	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)	

Revised: 1/2018 Scientific Solutions Global, LLC