

BIOTEMPER- menthol liquid
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 • 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 in one direction, not circular. • 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, Hydroxypropyl Cellulose NF, 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

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

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

<p>Drug Facts</p> <table border="1"> <tr> <td>Active Ingredient Menthol 10%</td> <td>Purpose Topical Analgesic</td> </tr> <tr> <td colspan="2">Uses For temporary relief of minor aches and pains of muscles and joints associated with • simple backache • arthritis • strains • sprains</td> </tr> <tr> <td colspan="2">Warnings</td> </tr> <tr> <td colspan="2">For external use only</td> </tr> <tr> <td colspan="2">Flammable keep away from fire or flame</td> </tr> <tr> <td colspan="2">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</td> </tr> <tr> <td colspan="2">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</td> </tr> <tr> <td colspan="2">Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away</td> </tr> <tr> <td colspan="2">If pregnant or breast-feeding, ask a health professional before use</td> </tr> <tr> <td colspan="2">Directions • Adults and children 2 years of age and older: Apply to affected area not more than 4 times daily in one direction, not circular • Children under 2 years of age, consult a physician • Massage not necessary • Shake well before use</td> </tr> <tr> <td colspan="2">Other Information • store in a cool and dry place with lid closed tightly</td> </tr> <tr> <td colspan="2">Inactive Ingredients Aloe Vera Oil, Arnica Flower Tincture, Boswellia Powder, Camphor, Frankincense Oil, Green Tea, Hydroxypropyl Cellulose NF, Isopropyl Alcohol, Lavender Oil, Propylene Glycol, Tea Tree Oil, Thymol, Vitamin E</td> </tr> <tr> <td colspan="2">Questions or Comments? Call us at: 1(516)543-3376 M-F 9am-6pm EST or E-mail: info@biotemper.com</td> </tr> </table>	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 • 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		Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away		If pregnant or breast-feeding, ask a health professional before use		Directions • Adults and children 2 years of age and older: Apply to affected area not more than 4 times daily in one direction, not circular • Children under 2 years of age, consult a physician • Massage not necessary • Shake well before use		Other Information • store in a cool and dry place with lid closed tightly		Inactive Ingredients Aloe Vera Oil, Arnica Flower Tincture, Boswellia Powder, Camphor, Frankincense Oil, Green Tea, Hydroxypropyl Cellulose NF, Isopropyl Alcohol, Lavender Oil, Propylene Glycol, Tea Tree Oil, Thymol, Vitamin E		Questions or Comments? Call us at: 1(516)543-3376 M-F 9am-6pm EST or E-mail: info@biotemper.com		 <p>PROUDLY MADE IN USA</p> <p>DISTRIBUTED BY: SCIENTIFIC SOLUTIONS GLOBAL, LLC CARLE PLACE, NY</p> <p>FOR ARTHRITIS, SPRAINS, SORE MUSCLES, BRUISES, & BACK PAIN</p> <p>BIOTEMPER®</p> <p>COLD PAIN RELIEF THERAPY MADE WITH HERBAL & HOMEOPATHIC INGREDIENTS NO NSAIDs, IBUPROFEN, ASPIRIN, OR SALICYLATE</p> <p>BIOTEMPER.COM 3 fl oz (89 mL)</p> 
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BIOTEMPER

menthol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71718-111
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 WHOLE (UNII: O80TY208ZW)	
FRANKINCENSE (UNII: R9XLF1R1WM)	
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)	
FRANKINCENSE OIL (UNII: 67ZYA5T02K)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
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:71718-111-01	89 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/03/2017	
2	NDC:71718-111-02	2 in 1 PACKAGE	08/03/2017	
2		89 mL in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:71718-111-03	3 in 1 PACKAGE	08/03/2017	
3		89 mL in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:71718-111-04	4 in 1 PACKAGE	08/03/2017	
4		89 mL in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:71718-111-05	6 in 1 PACKAGE	08/03/2017	
5		89 mL in 1 BOTTLE; Type 0: Not a Combination Product		
6	NDC:71718-111-06	12 in 1 PACKAGE	08/03/2017	
6		89 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	08/03/2017	

Labeler - Scientific Solutions Global Llc (097291290)**Establishment**

Name	Address	ID/FEI	Business Operations
Scientific Solutions Global Llc		097291290	manufacture(71718-111)

