

BIOTEMPER- menthol gel
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, 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

DEEP PENETRATING GEL

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



**PROUDLY
MADE IN
USA**
**Scientific
Solutions**
HERBAL MEDICINE
SCIENTIFIC SOLUTIONS
CORPORATION
CARLE PLACE, NY



ADVANCED FORMULA

DEEP PENETRATING GEL

FOR ARTHRITIS, SPRAINS, SORE MUSCLES,
AND ALL OTHER ACHES AND PAINS

BIOTEMPER®

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

BIOTEMPER.COM

4 fl oz (113 mL)

[illegible]

Ding Fats

Dietary Treatment

What to eat: **low-fat dairy products** (milk, yogurt, and cheese) **●** **lean meats** (chicken, turkey, and fish) **●** **whole grains** (oats, brown rice, and whole wheat bread) **●** **fruits and vegetables** (apples, bananas, and leafy greens) **●** **low-fat protein sources** (tofu, tempeh, and seitan) **●** **low-fat condiments** (mustard, ketchup, and salad dressing)

What to avoid: **high-fat dairy products** (butter, cream, and full-fat cheese) **●** **red meat** (beef, pork, and lamb) **●** **fried foods** (French fries, fried chicken, and fried fish) **●** **processed meats** (bacon, ham, and sausage) **●** **high-fat condiments** (mayonnaise, margarine, and butter) **●** **alcohol** (beer, wine, and spirits)

Diabetes

Dietary Treatment

What to eat: **whole grains** (oats, brown rice, and whole wheat bread) **●** **fruits and vegetables** (apples, bananas, and leafy greens) **●** **low-fat dairy products** (milk, yogurt, and cheese) **●** **lean meats** (chicken, turkey, and fish) **●** **low-fat protein sources** (tofu, tempeh, and seitan) **●** **low-fat condiments** (mustard, ketchup, and salad dressing)

What to avoid: **high-fat dairy products** (butter, cream, and full-fat cheese) **●** **red meat** (beef, pork, and lamb) **●** **fried foods** (French fries, fried chicken, and fried fish) **●** **processed meats** (bacon, ham, and sausage) **●** **high-fat condiments** (mayonnaise, margarine, and butter) **●** **alcohol** (beer, wine, and spirits)

[illegible]

PRODUCT MADE IN USA
 Scientific Solutions
 INFO@SCI.SOL.COM

DISTRIBUTED BY:
 Scientific Solutions
 Global Pacific
 CARE PLACE, NY

6 53981 75186 9

8 fl oz (237 mL)

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

BIOTEMPER®

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

BIOTEMPER.COM

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

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NO NSAIDS, IBUPROFEN, ASPIRIN, OR SALICYLATE

BIOTEMPER.COM

4 fl oz (118 mL)

[illegible]


 Scientific Solutions
 SPECIALTY CHEMICALS
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 (303) 751-1833
 www.scientificsolutionsusa.com

DISTRIBUTED BY
 SCIENTIFIC SOLUTIONS
 GLOBAL, LLC
 CANFIELD PLACE, NY


 Scientific Solutions USA

6 53981 75183 8

3.2 fl oz (946 mL)

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

BIOTEMPER®

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

BIOTEMPER.COM

[illegible]

Drug Facts

Active Ingredient	Purpose
MENTHOL	Relief of minor aches and pains

Warnings

Do not use on broken skin or on areas that are red, swollen, or itchy.

Directions

Apply a thin layer to the affected area. Rub gently until the gel is absorbed. Use 3 to 4 times a day.

Other information

Keep out of reach of children. Do not use if you are pregnant or nursing.

DEEP PENETRATING GEL

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

BOTEMPER[®]

COLD PAIN RELIEF THERAPY

MADE WITH HERBAL & HOMEOPATHIC INGREDIENTS

NO NSAIDS, IBUPROFEN, ASPIRIN, OR SALICYLATE

BIOTEMPER.COM

128 fl oz (3.75 L)

DRUG FACTS PANEL	
Drug Facts	
Active Ingredient	Purpose
Menthol 10%	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	
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 ■ 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, Isopropyl Alcohol, Lavender Oil, Propylene Glycol, Tea Tree Oil, Vitamin, Ethanol	
Questions or Comments?	
Call us at (1516) 543-3376 M-F 9am-6pm EST or E-mail: info@biotemper.com	

menthol gel

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71718-333
Route of Administration	TOPICAL		

Ingredient Name	Basis of Strength	Strength
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	10 g in 100 mL

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)	
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:71718-333-01	118 mL in 1 JAR; Type 0: Not a Combination Product	09/01/2017	
2	NDC:71718-333-02	2 in 1 PACKAGE	09/01/2017	
2		118 mL in 1 JAR; Type 0: Not a Combination Product		
3	NDC:71718-333-04	118 mL in 1 TUBE; Type 0: Not a Combination Product	09/01/2017	
4	NDC:71718-333-05	2 in 1 PACKAGE	09/01/2017	
4		118 mL in 1 TUBE; Type 0: Not a Combination Product		
5	NDC:71718-333-07	237 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	09/01/2017	
6	NDC:71718-333-09	452 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	09/01/2017	
7	NDC:71718-333-11	946 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	09/01/2017	
8	NDC:71718-333-13	1893 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	09/01/2017	
9	NDC:71718-333-15	3785 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	09/01/2017	
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(71718-333)

Revised: 1/2018

Scientific Solutions Global, LLC