BIOTEMPER FOOT CREAM- menthol cream 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 FOOT CREAM

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, Carbomer, Frankincense Oil, Green Tea, Hydroxypropyl Cellulose NF, Isopropyl Alcohol, Lavender Oil, Mineral Oil, Polysorbate-60, Preserved Water, Propylene Glycol, Tea Tree Oil, Thymol, Triethanolamine, 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

FOOT CREAM

NIGHT TIME RELIEF FOR SENSITIVE FEET

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



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, Carbomer, Frankincense Oil, Green Tea, Hydroxypropyl Cellulose NF, Isopropyl Alcohol, Lavender Oil, Mineral Oil, Polysorbate-60, Preserved Water, Propylene Glycol, Tea Tree Oil, Thymol, Triethanolamine, Vitamin E

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

BIOTEMPER FOOT CREAM

menthol cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71718-222
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Na	ıme	Basis of Strength	Strength
MENTHOL, UNSPECIFIED FORM (UNII: L7T10 UNII:L7T10 EIP3A)	EIP3A) (MENTHOL -	MENTHOL, UNSPECIFIED FORM	10 g in 100 mL

Inactive Ingredients		
Ingredient Name	Strength	
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)		
ARNICA MONTANA (UNII: O80TY208ZW)		
FRANKINCENSE (UNII: R9 XLF1R1WM)		
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)		
CARBO XYPO LYMETHYLENE (UNII: 0 A5MM307FC)		
FRANKINCENSE O IL (UNII: 67ZYA5T02K)		
GREEN TEA LEAF (UNII: W2ZU1RY8B0)		
HYDRO XYPRO PYL CELLULO SE, UNSPECIFIED (UNII: 9 XZ8 H6 N6 OH)		
ISOPROPYL ALCOHOL (UNII: ND2M416302)		
LAVENDER OIL (UNII: ZBP1YXW0H8)		
MINERAL OIL (UNII: T5L8T28FGP)		
POLYSORBATE 60 (UNII: CAL22UVI4M)		
WATER (UNII: 059QF0KO0R)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
TEA TREE OIL (UNII: VIF565UC2G)		
THYMOL (UNII: 3J50 XA376E)		
TROLAMINE (UNII: 9O3K93S3TK)		
.ALPHATOCOPHEROL (UNII: H4N855PNZ1)		

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:71718-222-01	57 mL in 1 JAR; Type 0: Not a Combination Product	09/01/2017	
2 NDC:71718-222-02	2 in 1 PACKAGE	09/01/2017	
2	57 mL in 1 JAR; 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 (71718-222)	

Revised: 1/2018 Scientific Solutions Global, LLC