

BIOTEMPER- menthol gel
BIOTEMPER FOOT CREAM- menthol gel
SSG Ventures Inc

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Biotemper



Menthol 10%.....Topical Analgesic

TOPICAL ANALGESIC WITH 10% MENTHOL

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

FAST ACTING COOLING PAIN RELIEF

FOR EXTERNAL USE ONLY

KEEP OUT OF REACH OF CHILDREN.

IF SWALLOWED, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER RIGHT AWAY

Adults & children 2 yrs 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.

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.

Store in a cool and dry place with lid closed



BIOTEMPER			
menthol gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81376-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	1 g in 10 mL

Inactive Ingredients

Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ARNICA MONTANA (UNII: O80TY208ZW)	
THYMOL (UNII: 3J50XA376E)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAMPHOR (NATURAL) (UNII: N20HL7Q941)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
TEA TREE OIL (UNII: VIF565UC2G)	
BOSWELLIA SACRA BARK (UNII: 1UK28DX728)	
FRANKINCENSE OIL (UNII: 67ZYA5T02K)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	

Product Characteristics

Color	white (Opaque)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81376-001-01	113 mL in 1 JAR; Type 0: Not a Combination Product	01/01/2021	
2	NDC:81376-001-02	452 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	01/01/2021	
3	NDC:81376-001-03	1900 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	01/01/2021	
4	NDC:81376-001-04	89 mL in 1 TUBE, WTH APPLICATOR; Type 0: Not a Combination Product	01/01/2021	
5	NDC:81376-001-05	118 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	01/01/2021	
6	NDC:81376-001-06	118 mL in 1 TUBE; Type 0: Not a Combination Product	01/01/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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unapproved drug other	01/01/2021
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BIOTEMPER FOOT CREAM

menthol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81376-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	1 g in 10 mL

Inactive Ingredients

Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ARNICA MONTANA (UNII: O80TY208ZW)	
THYMOL (UNII: 3J50XA376E)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAMPHOR (NATURAL) (UNII: N20HL7Q941)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
TEA TREE OIL (UNII: VIF565UC2G)	
BOSWELLIA SACRA BARK (UNII: 1UK28DX728)	
FRANKINCENSE OIL (UNII: 67ZYA5T02K)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
WATER (UNII: 059QF0KO0R)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	

Product Characteristics

Color	white (Opaque)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81376-002-01	57 mL in 1 JAR; Type 0: Not a Combination Product	01/01/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		01/01/2021	

Labeler - SSG Ventures Inc (047626115)

Establishment

Name	Address	ID/FEI	Business Operations
SSG Ventures Inc		047626115	manufacture(81376-001, 81376-002)

Revised: 4/2021

SSG Ventures Inc