

BIOTEMPER- menthol, camphor liquid

Biotemper

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 - Herbal Pain Relief Therapy

Drug Facts

Active Ingredients

Menthol USP 10%.

Camphor USP 2%

Purpose

Topical Analgesic

Keep out of the reach of children: If ingested, seek medical help and contact a Poison Control Center immediately.

Uses : Soothing temporary relief from minor aches and pains associated with • sore muscles • strains • joint discomfort • arthritis • backache • tendonitis

Warning: For external use only.

Flammable: Keep away from excessive heat or open flames.

Ask a doctor before using if you have: Sensitive skin If pregnant or breast feeding: Ask a health professional before use.

When using this product: • Avoid contact with eyes or mucous membrane. • Do not apply to wounds or damaged skin. • Do not use with other ointments, creams, sprays or liniments. • Do not apply to irritated skin or if excessive irritation develops. • Do not bandage. • Wash hands after use with cool water • Do not use with heating pad or device.

Stop use and ask a doctor if: Condition worsens or if symptoms persist for more than 7 days or clear up and reoccur.

Directions: Adult and Children 2 years age and older: Rub a thin film over affected areas not more than 4 times daily: Massage not necessary Children under 2 years of age: Consult physician.

Inactive Ingredients: Aloe Vera Oil, Arnica Flower Tincture, Hydroxypropyl Cellulose NF, Isopropyl Alcohol, Propylene Glycol USP

Other information: Store in a cool and dry place with the lid closed tightly.

NO NSAIDS, IBUPROFEN, ASPIRIN OR SALICYLATE

FOR ARTHRITIS/BACK PAIN/ BRUISES/SORE MUSCLES/ SPORTS SPRAINS

Shake well before each use. Apply by rolling in only one direction.

Do not use in a circular motion

Packaging

BIO TEMPER

HERBAL PAIN RELIEF THERAPY

3FL oz/89ML | Roll On

NO NSAIDS, IBUPROFEN
ASPIRIN OR SALICYLATE

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SORE MUSCLES | SPORTS SPRAINS**

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biotemper.com

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Manufactured in the U.S.A.

No Animal Testing



BIO TEMPER

menthol, camphor liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70744-516
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	10 g in 100 mL
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	2 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
HYDROXYPROPYL CELLULOSE (TYPE E) (UNII: 66O7AQV0RT)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70744-516-01	89 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	07/01/2016	

Labeler - Biotemper (080260740)**Establishment**

Name	Address	ID/FEI	Business Operations
Pharmacena Labs, LLC		075596057	manufacture(70744-516)

Revised: 6/2016

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