

BIO 2 BRAZILIAN HEAT BRAZILIAN HEAT- menthol liquid

Bio 2

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.

Drug Facts

Active Ingredient

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Menthol 7.0%

Purpose

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External analgesi

Use

- For the temporary relief of pain and soreness.
- May help distract from pain.
- May provide a cooling sensation.

Warnings

Only for external use.

Flammable. Keep away from heat or flame.

- Do not apply to irritated skin or if excessive irritation develops
- Avoid getting into the eyes or mucos membranes.

Stop use and ask a physician if

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symptoms persist.

Keep out of reach of children

If swallowed, seek medical advice or contact a Poison Control Center immediately.

Directions

Spray a light mist over the affected area up to 6 times daily. Allow to

air dry.

Alcohol, Dimethyl Sulfone (MSM),
Eucalyptus Oil, Gelidiella acerosa,
Hydrogen Peroxide and Chlorine
Dioxide, Hypnea musciformis,
Magnesium, Peppermint Oil,
Sargassum filipendula,
Sodium, Sorbitol, Water, Zinc

Questions:

Paso Robles, CA 93446 USA
805.238.0300
www.bio2USA.com
Made in the U.S.A.
Placeholder Text

- Deep penetrating pain relief topical spray.
- Fast relief from minor arthritis, backache, muscle and joint pain.
- Ideal for minor strains.
- Safe for all ages.

Inactive Ingredients

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Dioxide, Hypnea musciformis,
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Sargassum filipendula,
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NDC# 24488-036-74

DRUG FACTS

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Menthol 7.0%	External analgesic

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Directions:

Spray a light mist over the affected area up to 6 times daily. Allow to air dry.

Distributed Exclusively by:
BIO2 International, Inc.
San Luis Obispo, CA 93401 U.S.A.
805.549.0275
www.bio2USA.com

menthol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:24488-036
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Menthol (UNII: L7T10EIP3A) (Menthol - UNII:L7T10EIP3A)	Menthol	4.2 mL in 60 mL

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
GELIDIELLA ACEROSA (UNII: T91K54D6M1)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	
CHLORINE DIOXIDE (UNII: 8061YMS4RM)	
HYPNEA MUSCIFORMIS (UNII: W6FF9R1FJV)	
MAGNESIUM (UNII: I38ZP9992A)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
SARGASSUM FILIPENDULA (UNII: 55P66J5H7N)	
SODIUM (UNII: 9NEZ333N27)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KO0R)	
ZINC (UNII: J41CSQ7QDS)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24488-036-74	60 mL in 1 BOTTLE, WITH APPLICATOR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	03/15/2012	

Labeler - Bio 2 (961956229)

Registrant - Creations Garden Natural Products, Inc. (961956229)

Establishment

Name	Address	ID/FEI	Business Operations
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