

BIOMEGA- capsaicin cream
Concept Laboratories, Inc.

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.

BioMega™

Drug Facts

Active ingredient

Capsicum Oleoresin 0.0625%
(Containing Capsaicin 0.025%)

Purpose

Topical Analgesic

Uses

for the temporary relief of minor aches and pains of muscles and joints associated with

- simple backache
- arthritis
- strains
- sprains

Warnings

For external use only.

- This is not a face cream. Do not apply to the face.
- Do not use if allergic to chili peppers or if past allergic reaction to capsaicin.
- Do not apply to wounds or damaged, broken, sunburned, chapped or irritated skin.
- Do not bandage tightly.
- Do not apply within 1 hour before or after bath, shower, hot tub, sauna or vigorous exercise. Warm water, perspiration or open pores can intensify the impact of this product and burning sensation.
- Do not use with heating pad, hot water bottle or other source of heat Doing so can increase risk of serious burns.

When using this product

- Do not get into eyes and avoid contact with other mucous membranes. If contact occurs or if pain, discomfort or skin redness occurs, continually rinse with cool water and seek medical help.

Discontinue use and consult a doctor if condition worsens or if symptoms persist for more than 7 days or clear up and occur again within a few days. Stop using and get immediate medical attention if experience burning, pain, swelling or blistering of the skin. Rare cases of severe burning or blistering have been reported.

If pregnant, breast-feeding or any medical conditions exist ask a health professional before use.

Keep out of reach of children and pets. If swallowed, get medical help or contact a Poison Control Center right away. If inhaled, remove to fresh air. If breathing is difficult get medical attention

immediately.

Directions

- Rotate pump's spout counter-clockwise slightly to unlock; clockwise to lock.
- Before using on children under 18 years of age consult a physician.
- Apply sparingly to affected area not more than 4 times daily. However, for first use, apply to small skin area to test for sensitivity or skin reaction.
- Gently massage into the skin until fully absorbed.
- Wash hands with soap and water thoroughly after each application to avoid spreading to the eyes or other sensitive mucous membranes.
- A burning sensation may occur upon initial application but generally disappears with continued use. For a severe burning discomfort remove excess product with a soft cloth and cooking oil.

Inactive ingredients

Water (Aqua), Butylene Glycol, Glycerin, Aloe Barbadensis Leaf Juice, Helianthus Annuus (Sunflower) Seed Oil, Medicago Sativa (Alfalfa) Extract, Arnica Montana Flower Extract, Cymbopogon Schoenanthus Stem/Leaf/Flower Extract, Rosmarinus Officinalis (Rosemary) Leaf Extract, Mentha Piperita (Peppermint) Leaf Extract, Panax Ginseng Root Extract, Ginkgo Biloba Leaf Extract, Linum Usitatissimum (Linseed) Seed Extract, Celosia Argentea Seed Extract, Euterpe Oleracea Fruit Extract, Mentha Piperita Leaf Extract, Glucosamine HCl, Dimethyl Sulfone, Hydrolyzed Corn Starch, Lauryl Laurate, Methyl Diisopropyl Propionamide, Ethyl Mentane Carboxamide, Menthyl Lactate, Hydrated Silica, Zea Mays (Corn) Starch, Hydrolyzed Corn Starch Octenylsuccinate, Cetearyl Isononanoate, Ceteareth-20, Cetearyl Alcohol, Glyceryl Stearate, Ceteareth-12, Cetyl Palmitate, Emu Oil, Polysorbate 20, Acrylates/C 10-30 Alkyl Acrylate Crosspolymer, Tocopheryl Acetate, Disodium EDTA, Phenoxyethanol, Caprylyl Glycol, Ethylhexylglycerin, Hexylene Glycol, Sodium Hydroxide.

Questions or comments?

Call toll-free 1-877-630-9788 or visit us at www.biomegard.com

Manufactured for SCI Plano, TX 75024

Manufactured by: Concept Laboratories, Inc. Chicago, IL 60642

PRINCIPAL DISPLAY PANEL - 237 mL Bottle Label

BIOMEGA™

Penetrating

HEAT PAIN THERAPY Cream

with Heating Capsaicin

- Omegas 3,6 & 9
- With Natural Ingredients
- Ice Pearls™ Technology
For Hours Of Therapy

Paraben-free topical analgesic for

Arthritis • Joint Pain • Muscle Ache • Cramps

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Arthritis • Joint Pain • Muscle Ache • Cramps

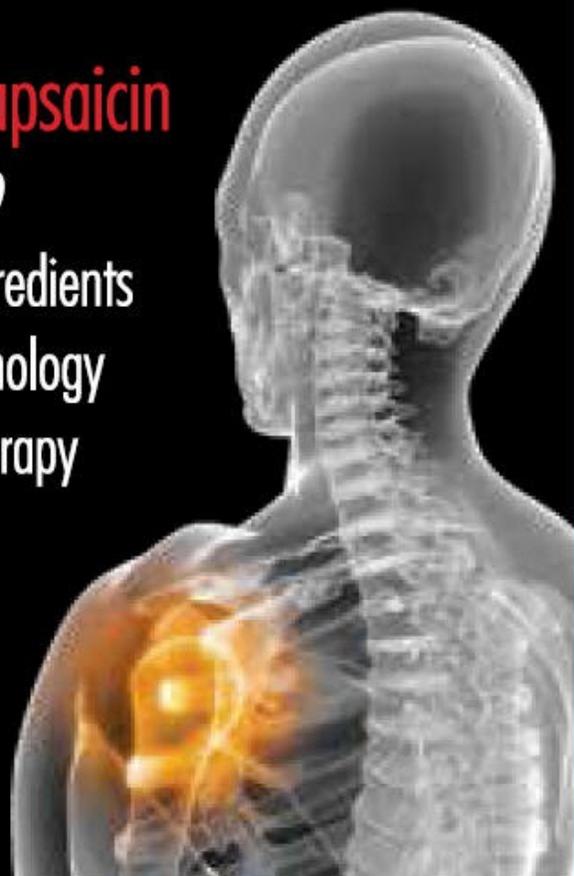
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8 FL OZ (237 mL)

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Manufactured for: SCI
Plano, TX 75024
Manufactured by: Concept Laboratories, Inc.
Chicago, IL 60642

ITEM #1654454R1



BIOMEGA

capsaicin cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:64058-355
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Capsaicin (UNII: S07O44R1ZM) (Capsaicin - UNII:S07O44R1ZM)	Capsaicin	2.5 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
METHYL DIISOPROPYL PROPIONAMIDE (UNII: 6QOP5A9489)	
ETHYL MENTHANE CARBOXYAMIDE (UNII: 6S7S02945H)	
MENTHYL LACTATE, (-)- (UNII: 2BF9E65L7I)	
LAURYL LAURATE (UNII: GPW77G0937)	
STARCH, CORN (UNII: O8232NY3SJ)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
GLUCOSAMINE HYDROCHLORIDE (UNII: 750W5330FY)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
GLYCERIN (UNII: PDC6A3C0OX)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
ALFALFA (UNII: DJO934BRBD)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
CYMOPOGON SCHOENANTHUS TOP (UNII: 9SJIILW39W)	
ROSEMARY (UNII: IJ67X351P9)	
MENTHA PIPERITA LEAF (UNII: A389O33LX6)	
ASIAN GINSENG (UNII: CUQ3A77YXI)	
GINKGO (UNII: 19FUJ2C58T)	
FLAX SEED (UNII: 4110YT348C)	

CELOSIA ARGENTEA SEED (UNII: O1H314U8M2)
ACAI (UNII: 46AM2VJ0AW)
EDETATE DISODIUM (UNII: 7FLD91C86K)
EMU OIL (UNII: 344821WD61)
POLYSORBATE 20 (UNII: 7T1F30V5YH)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
Ethylhexylglycerin (UNII: 147D247K3P)
Hexylene Glycol (UNII: KEH0A3F75J)
CETEARYL ISONONANOATE (UNII: P5O01U99NI)
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)
CETEARETH-12 (UNII: 7V4MR24V5P)
CETYL PALMITATE (UNII: 5ZA2S6B08X)
SODIUM HYDROXIDE (UNII: 55X04QC32I)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64058-355-18	238 g in 1 BOTTLE; Type 0: Not a Combination Product	08/31/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part348	08/31/2016	

Labeler - Concept Laboratories, Inc. (962282612)

Establishment

Name	Address	ID/FEI	Business Operations
Concept Laboratories, Inc.		962282612	MANUFACTURE(64058-355)

Revised: 9/2016

Concept Laboratories, Inc.