

OMEGA 3- 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.

Omega 3 Cream

Drug Facts

Active ingredient

Capsicum Oleoresin 0.0625% (Containing Capsaicin 0.025%)

Purpose

Pain Relieving

Uses

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

- simple backache
- arthritis
- strains
- sprains
- bruises

Warnings

For external use only.

- do not apply to wounds or damaged skin
- do not bandage tightly
- do not use with heating pad, pack, wrap, hot water bottle or any heating element

When using this product do not get into eyes

- avoid contact with other mucous membranes

Discontinue use and ask a doctor if condition worsens or if symptoms persist for more than 7 days or 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 nursing**, seek the advice of a health professional before using

Directions

- Children under 12 years of age consult a physician
- Apply a thin layer to affected area not more than 3 to 4 times daily
- Gently massage into the skin until fully absorbed
- Wash hands with soap and water after each application to avoid spreading to the eyes or other sensitive mucous membranes

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 1-888-373-8831

Manufactured by:
Concept Laboratories, Inc.
Chicago, IL 60642 (USA)

PRINCIPAL DISPLAY PANEL - 59 mL Bottle Label

OMEGA

3

PAIN RELIEVING CREAM

*Fast, Long-Lasting Relief
for Muscle & Joint Pain*

with Omega-3 Fatty Acids

Also contains

MSM, Glucosamine

& Capsaicin

- **Powerful Anti-Inflammatory**
- **Soothing Nutritive Abilities**
- **Natural Antioxidant Protection**
- **Safe Alternative to Pills**

2 FL OZ (59mL)

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Other information

See enclosed pamphlet for complete Warnings, Directions and Inactive Ingredients

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#CL9893R1

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 Chicago, IL 60642 (USA)

BG-CL9893R1

OMEGA 3

capsaicin cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:64058-353
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: 059QF0K00R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
METHYL DIISOPROPYL PROPIONAMIDE (UNII: 6QOP5A9489)	
ETHYL MENTHANE CARBOXAMIDE (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)	
CYMBOPOGON SCHOENANTHUS TOP (UNII: 9SJ1LW39W)	
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: P5O01U99N)
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)
CETEARETH-12 (UNII: 7V4MR24V5P)
CETYL PALMITATE (UNII: 5ZA2S6B08X)
SODIUM HYDROXIDE (UNII: 55X04QC32)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64058-353-12	59 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/08/2016	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part348	07/08/2016	

Labeler - Concept Laboratories, Inc. (962282612)

Establishment			
Name	Address	ID/FEI	Business Operations
Concept Laboratories, Inc.		962282612	MANUFACTURE(64058-353)