

MY OMEGA 3 RUB- menthol, unspecified form and camphor (synthetic) 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.

My Omega[®] 3
Rub

Drug Facts

<i>Active ingredient</i>	<i>Purpose</i>
Menthol 12%	Pain Relieving
Camphor 6%	Pain Relieving

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.

- do not apply to wounds or damaged skin
- do not bandage tightly

When using this product do not get into eyes

- avoid contact with other mucous membranes

Flammable

Keep from heat and flame.

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

- **Rotate pump's spout counter-clockwise slightly to unlock; clockwise to lock**
- Children under 12 years of age consult a physician
- Apply liberally 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), Aloe Barbadensis Leaf Juice, SD Alcohol 40-B, Propylene Glycol, Mentha Piperita (Peppermint) Oil, Arnica Montana Flower Extract, Carbomer, Acrylates Copolymer, Corn Starch Modified, Linum Usitatissimum (Linseed) Seed Oil, Euterpe Oleracea Fruit Oil, PPG-2 Hydroxyethyl Cocamide, Rosmarinus Officinalis (Rosemary) Leaf Oil, Hydrolyzed Corn Starch, Lauryl Laurate, Methyl Diisopropyl Propionamide, Ethyl Mentane Carboxamide, Menthyl Lactate, Hydrated Silica, Zea Mays (Corn) Starch, Hydrolyzed Corn Starch Octenylsuccinate.

Questions or comments?

Call toll-free 1-888-373-8831 or visit us at www.myomegapain.com

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

PRINCIPAL DISPLAY PANEL - 237 ml Bottle Label

MYOMEGA[®]

OMEGA[™]
3⁺

Triple Strength
Pain
Relief
Rub

with:

- ***Menthol & Camphor***
- ***Anti-Inflammatory Omegas 3, 6 & 9***
- ***Açai Extract***
- ***and Timed-Release***

IcePearls[™]

8 FL OZ (237 ml)

Paraben-free topical analgesic for:
Strains • Sprains • Muscle Pain • Tension

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Camphor 6%

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Pain Relieving
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Manufactured by:
Concept Laboratories, Inc.
Chicago, IL 60642 (USA) #CL9901R1



MY OMEGA®

OMEGA™ 3+

Triple Strength Pain Relief Rub

with:

- **Menthol & Camphor**
- **Anti-Inflammatory Omegas 3, 6 & 9**
- **Açai Extract**
- **and Timed-Release**

IcePearls™

8 FL OZ (237 ml)

Paraben-free topical analgesic for:
Strains • Sprains • Muscle Pain • Tension

MY OMEGA 3 RUB

menthol, unspecified form and camphor (synthetic) cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:64058-345
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	0.12 g in 1 g
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	0.06 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
ALCOHOL (UNII: 3K9958V90M)	
STARCH, CORN (UNII: O8232NY3SJ)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
LINSEED OIL (UNII: 84XB4DV00W)	
ROSEMARY OIL (UNII: 8LGU7VM393)	
ACAI OIL (UNII: Z0W6766A2W)	
PPG-2 HYDROXYETHYL COCAMIDE (UNII: 34N07GUJ3X)	
METHYL DIISOPROPYL PROPIONAMIDE (UNII: 6QOP5A9489)	
ETHYL MENTHANE CARBOXAMIDE (UNII: 6S7S02945H)	
MENTHYL LACTATE, (-)- (UNII: 2BF9E65L7I)	
LAURYL LAURATE (UNII: GPW77G0937)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64058-345-68	234 g in 1 BOTTLE; Type 0: Not a Combination Product	06/27/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part348	06/27/2016	

Labeler - Concept Laboratories, Inc. (962282612)

Establishment

Name	Address	ID/FEI	Business Operations
Concept Laboratories, Inc.		962282612	MANUFACTURE(64058-345)

Revised: 9/2016

Concept Laboratories, Inc.