# RETADOLOR- menthol, unspecified form and camphor (synthetic) cream LACAR SALES & MARKETING 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.

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Retadolor™ CREAM

**Drug Facts** 

Active ingredient	Purpose
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
- strain
- sprains
- bruises

# 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

- Apply liberally to affected area not more than 4 times daily unless otherwise directed by your physician or pharmacist
- 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), SD Alcohol 40-B, Aloe Barbadensis Leaf Juice 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 Menthane Carboxamide, Menthyl Lactate, Hydrated Silica, Zea Mays (Corn) Starch, Hydrolyzed Corn Starch Octenylsuccinate.

# PRINCIPAL DISPLAY PANEL - 85 g Bottle Label

RETADOLOR<sup>TM</sup>
The Anti-Pain<sup>TM</sup>

#### PENETRATING COOL THERAPY CREAM

Topical Analgesic for the Relief of TENSION, STRAINS, SPRAINS & MUSCLE PAIN

Contains Powerful Menthol & Camphor with Vanishing Scent

ANTI-INFLAMMATORY OMEGA 3, 6 & 9 with IcePearls

NET WT. 3 OZ (85g)



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# Drug Facts cont.

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Exclusively manufactured for LaCar Sales & Marketing Inc. by Concept Laboratories, Inc., Chicago, IL 60642 www.retadolor.com

#CL9957-R1

# RETADOLOR

menthol, unspecified form and camphor (synthetic) cream

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:69279-241

Route of Administration TOPICAL

# Active Ingredient/Active Moiety Ingredient Name Basis of Strength MENTHOL, UNSPECIFIED FORM (UNII: L7T10 EIP3A) (MENTHOL, UNSPECIFIED FORMUNII:L7T10 EIP3A) CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) UNII:5TJD82A1ET) CAMPHOR (SYNTHETIC)

Inactive Ingredients		
Ingredient Name	Strength	
Water (UNII: 059QF0KO0R)		
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)		
PROPYLENE GLYCOL (UNII: 6 DC9 Q167V3)		
PEPPERMINT O IL (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 CARBO XAMIDE (UNII: 6S7S02945H)	
MENTHYL LACTATE, (-)- (UNII: 2BF9E65L7I)	
LAURYL LAURATE (UNII: GPW77G0937)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	

	Packaging			
1	# Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
	NDC:69279-241-13	85 g in 1 BOTTLE; Type 0: Not a Combination Product	02/08/2017	
:	NDC:69279-241-44	113 g in 1 BOTTLE; Type 0: Not a Combination Product	02/08/2017	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH NOT FINAL	part348	02/08/2017		

# **Labeler -** LACAR SALES & MARKET ING INC. (795293435)

# Registrant - Concept Laboratories, Inc. (962282612)

Establishment				
Name	Address	ID/FEI	Business Operations	
Concept Laboratories, Inc.		962282612	MANUFACTURE(69279-241)	

Revised: 3/2017 LACAR SALES & MARKETING INC.