

**RETADOLOR PENETRATING COOL THERAPY- menthol 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.*

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**RETADOLOR**  
**The Anti-Pain**  
**PENETRATING COOL THERAPY CREAM**

<b>Active ingredient</b>	<b>Purpose</b>
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
- 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), 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, Methyl Diisopropyl Propionamide, Ethyl Methane Carboximide, Methyl Lactate, Lauryl Laurate, Zea Mays (Corn) Starch, Hydrolyzed Corn Starch, Hydrolyzed Starch Octrenylsuccinate, Phenoxyethanol, DMDM Hydantoin, Iodopropynyl Butylcarbamate

Exclusively manufactured for  
LaCar Sales & Marketing Inc.  
by Concept Laboratories, Inc.  
Chicago, IL 60642  
www.retadolor.com  
#CL9957

**PRINCIPAL DISPLAY PANEL - 85g Bottle Label**

**RETADOLOR**

NDC 64058-241-13

**The Anti-Pain**

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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## RETADOLOR PENETRATING COOL THERAPY

menthol and camphor (synthetic) cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:64058-241
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Menthol</b> (UNII: L7T10EIP3A) (Menthol - UNII:L7T10EIP3A)	Menthol	10.2 g in 85 g
<b>Camphor (Synthetic)</b> (UNII: 5TJD82A1ET) (Camphor (Synthetic) - UNII:5TJD82A1ET)	Camphor (Synthetic)	5.1 g in 85 g

### Inactive Ingredients

Ingredient Name	Strength
<b>Water</b> (UNII: 059QF0KO0R)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>ARNICA MONTANA FLOWER</b> (UNII: OZ0E5Y15PZ)	
<b>DMDM HYDANTOIN</b> (UNII: BYR0546TOW)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	

<b>IODOPROPYNYL BUTYLCARBAMATE</b> (UNII: 603P14DHEB)	
<b>METHYL DIISOPROPYL PROPIONAMIDE</b> (UNII: 6QOP5A9489)	
<b>LAURYL LAURATE</b> (UNII: GPW77G0937)	
<b>CARBOMER HOMO POLYMER TYPE C</b> (UNII: 4Q93RCW27E)	
<b>PEPPERMINT OIL</b> (UNII: AV092KU4JH)	
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>LINSEED OIL</b> (UNII: 84XB4DV00W)	
<b>ROSEMARY OIL</b> (UNII: 8LGU7VM393)	
<b>ACAI OIL</b> (UNII: Z0W6766A2W)	

<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64058-241-13	85 g in 1 BOTTLE		

<b>Marketing Information</b>			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part348	07/27/2009	

**Labeler** - Concept Laboratories, Inc. (962282612)

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
Concept Laboratories, Inc.		962282612	MANUFACTURE