RETADOLOR PAIN RELIEF- capsaicin 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.

RETADOLOR™ Pain Relief

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

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 a thin layer 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, Mentha Piperita (Peppermint) Oil, Arnica Montana Flower Extract, Acrylates Copolymer, Linum Usitatissmum (Linseed) Seed Oil, Euterpe Oleracea Fruit Oil, PPG-2 Hydroxyethyl Cocamide, Rosmarinus Officinalis (Rosemary) Leaf Oil, Methyl Diisopropyl Propionamide, Ethyl Menthane Carboxamide, Menthyl Lactate, Lauryl Laurate, Zea Mays (Corn) Starch, Hydrolyzed Corn Starch, Hydrolyzed Starch Octenylsuccinate, Acrylates C10-30 Alkyl Acrylate Crosspolymer, Triethanolamine, Phenoxyethanol, DMDM Hydantoin, Iodopropynyl Butylcarbamate.

PRINCIPAL DISPLAY PANEL - 85 g Bottle Label

 $\begin{array}{c} \textbf{RETADOLOR}^{\text{TM}} \\ \textbf{The Anti-Pain}^{\text{TM}} \end{array}$

PENETRATING HEAT THERAPY CREAM

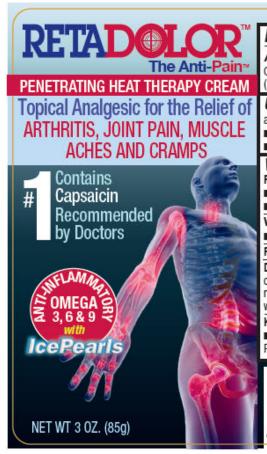
Topical Analgesic for the Relief of ARTHRITIS, JOINT PAIN, MUSCLE ACHES AND CRAMPS

#1

Contains Capsaicin Recommended by Doctors

ANTI-INFLAMMATORY OMEGA
3, 6 & 9
with
IcePearls

NET WT 3 OZ. (85g)



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025% Pain 025%) Relieving

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Drug Facts cont.

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Exclusively manufactured for LaCar Sales & Marketing Tampa, FL 33647 (USA)

#CL9928-R2

RETADOLOR PAIN RELIEF

capsaicin cream

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:69279-144

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Capsaicin (UNII: S07O44R1ZM) (Capsaicin - UNII:S07O44R1ZM)	Capsaicin	0.25 mg in 1 g

Inactive Ingredients	
Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
METHYL DIISOPROPYL PROPIONAMIDE (UNII: 6QOP5A9489)	
LAURYL LAURATE (UNII: GPW77G0937)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
DMDM HYDANTO IN (UNII: BYR0546TOW)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	

MENTHYL LACTATE, (-)- (UNII: 2BF9E65L7I)	
STARCH, CORN (UNII: O8232NY3SJ)	
PPG-2 HYDROXYETHYL COCAMIDE (UNII: 34N07GUJ3X)	
TROLAMINE (UNII: 903K93S3TK)	
ALCOHOL (UNII: 3K9958V90M)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
LINSEED OIL (UNII: 84XB4DV00W)	
ACAI OIL (UNII: Z0W6766A2W)	
ETHYL MENTHANE CARBO XAMIDE (UNII: 6S7S02945H)	
ROSEMARY OIL (UNII: 8LGU7VM393)	

ı	Packaging			
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:69279-144- 13	85 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part348	08/07/2015	

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

Establishment			
Name	Address	ID/FEI	Business Operations
Concept Laboratories, Inc.		962282612	MANUFACTURE(69279-144)

Revised: 8/2015 LACAR SALES & MARKETING INC.