

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 Usitatissimum (Linseed) Seed Oil, Euterpe Oleracea Fruit Oil, PPG-2 Hydroxyethyl Cocamide, Rosmarinus Officinalis (Rosemary) Leaf Oil, Methyl Diisopropyl Propionamide, Ethyl Mentane 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

RETADOLOR™

The Anti-Pain™

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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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 HYDANTOIN (UNII: BYR0546TOW)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

MENTHYL LACTATE, (-) (UNII: 2BF9E65L7I)	
STARCH, CORN (UNII: O8232NY3SJ)	
PPG-2 HYDROXYETHYL COCAMIDE (UNII: 34N07GUJ3X)	
TROLAMINE (UNII: 9O3K93S3TK)	
ALCOHOL (UNII: 3K9958V90M)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
LINSEED OIL (UNII: 84XB4DV00W)	
ACAI OIL (UNII: Z0W6766A2W)	
ETHYL MENTHANE CARBOXAMIDE (UNII: 6S7S02945H)	
ROSEMARY OIL (UNII: 8LGU7VM393)	

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 & MARKETING INC. (795293435)

Establishment

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

Revised: 8/2015

LACAR SALES & MARKETING INC.