

DERMACINRX PENETRAL CREAM- capsaicin cream
PureTek Corporation

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.

Penetral Cream

10/14- added new size 118 mL

10/19-Updating marketing date for new size 118ml

Active ingredient

Capsicum Oleoresin 0.0625% (Containing Capsaicin 0.025%)

Purpose

Topical Analgesic

Uses

for the temporary relief of minor aches and pains of muscles and joints associated with simple backache, arthritis, strains and sprains

Warnings

For external use only

- This is not a face cream. Do not apply to the face.
- Do not use if allergic to chili peppers or if past allergic reaction to capsaicin.
- Do not apply to wounds or damaged, broken, sunburned, chapped or irritated skin.
- Do not bandage tightly.
- Do not apply within 1 hour before or after bath, shower, hot tub, sauna or vigorous exercise. Warm water, perspiration or open pores can intensify the impact of this product and cause a burning sensation.
- Do not use with heating pad, hot water bottle or other source of heat. Doing so can increase risk of serious burns.

When using this product

do not get into eyes and avoid contact with other mucous membranes. If contact occurs or if pain, discomfort or skin redness occurs, continually rinse with cool water and seek medical help.

Discontinue use and consult a doctor if

condition worsens or if symptoms persist for more than 7 days or clear up and occur

again within a few days. Stop using and get immediate medical attention if experience burning, pain, swelling or blistering of the skin. Rare cases of severe burning or blistering have been reported. If pregnant, breast-feeding or any medical conditions exist, ask a health professional before use.

Keep out of reach of children and pets.

If swallowed, get medical help or contact a Poison Control Center right away. If inhaled, remove to fresh air. If breathing is difficult, get medical attention immediately.

Directions

- Rotate pump's spout counter-clockwise slightly to unlock; clockwise to lock.
- Before using on children under 18 years of age, consult a physician.
- Apply sparingly to affected area not more than 4 times daily. However, for first use, apply to small area to test for sensitivity or skin reaction.
- Gently massage into the skin until fully absorbed.
- Wash hands with soap and water thoroughly after each application to avoid spreading to the eyes or other sensitive mucous membranes.

Other information

WARNING: FLAMMABLE PRODUCT

Store in a cool well ventilated area away from heat. Keep away from sparks or open flame.

Inactive ingredients

Acrylates Copolymer, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aloe Barbadensis (Aloe Vera) Leaf Juice, Aqua (Purified Water), Arnica Montana Flower Extract, Ethyl Alcohol, Ethyl Menthane Carboxamide, Euterpe Oleracea (Acai) Fruit Oil, Glycerin, Hydrated Silica, Hydrolyzed Corn Starch, Hydrolyzed Corn Starch Octenylsuccinate, Lauryl Laurate, Linum Usitatissimum (Linseed) Seed Oil, Mentha Piperita (Peppermint) Oil, Menthyl Lactate, Methyl Diisopropyl Propionamide, Phenoxyethanol, PPG-2 Hydroxyethyl Cocamide, Rosmarinus Officinalis (Rosemary) Oil, Triethanolamine, Zea Mays (Corn) Starch.

Questions or comments?

Call toll-free 1-877-921-7873 or visit us at www.dermacinrx.com

DermacinRx® Penetral™ Cream

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Manufactured in the USA by: List No:31016GLA
Puretek Corporation, Rev:29343-02
San Fernando, CA 91340



NDC 59088-310-16

DERMACIN[®]

**Penetral[™]
Cream**

Capsaicin 0.025%

Topical use only

8 FL OZ (237mL)

Manufactured in the USA by:
Puretek Corporation
San Fernando, CA 91340
For questions or information
call toll-free: 877-921-7873

List No: 310081AA
Rev: 38342



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NDC 59088-310-08



**Penetral™
Cream**

Capsaicin 0.025%

Topical use only

4 FL OZ (118ML)

DERMACINRX PENETRAL CREAM

capsaicin cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59088-310
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAPSICUM OLEORESIN (UNII: UW86K581WY) (CAPSICUM OLEORESIN - UNII:UW86K581WY)	CAPSAICIN	0.25 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
AMYOLOPECTIN, UNSPECIFIED SOURCE (UNII: 4XO4QFV777)	
STARCH, CORN (UNII: O8232NY3SJ)	
HYDROXYETHYL BEHENAMIDOPROPYL DIMONIUM CHLORIDE (UNII: 9CO8OUL4TH)	
LAURYL LAURATE (UNII: GPW77G0937)	
TROLAMINE (UNII: 9O3K93S3TK)	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J)	
WATER (UNII: 059QF0KO0R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
ALCOHOL (UNII: 3K9958V90M)	
ETHYL MENTHANE CARBOXAMIDE (UNII: 6S7S02945H)	
ACAI OIL (UNII: Z0W6766A2W)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
GLYCERIN (UNII: PDC6A3C0OX)	
CORN SYRUP (UNII: 9G5L16BK6N)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
MENTHYL LACTATE, (-)- (UNII: 2BF9E65L7I)	
METHYL DIISOPROPYL PROPIONAMIDE (UNII: 6QOP5A9489)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PPG-2 HYDROXYETHYL COCAMIDE (UNII: 34N07GUJ3X)	
ROSEMARY OIL (UNII: 8LGU7VM393)	
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)	
OCTENYLSUCCINIC ANHYDRIDE (UNII: 4YWS14FAXH)	
LINSEED OIL (UNII: 84XB4DV00W)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59088-310-16	237 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/09/2015	
2	NDC:59088-310-08	118 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	10/25/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	06/09/2015	

Labeler - PureTek Corporation (785961046)