

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.

DemacinRx[®] Penetral[™] Cream

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 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 product immediately and get medical attention if experiencing 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, Ethylhexylglycerin, Euterpe Oleracea (Acai) Fruit Oil, Glycerin, Hydroxyethyl Behenamidopropyl Dimonium Chloride, Lauryl Laurate, Linum Usitatissimum (Flax) Seed Oil, Mentha Piperita (Peppermint) Oil, Menthyl Lactate, Methyl Diisopropyl Propionamide, Phenoxyethanol, PPG-2 Hydroxyethyl Cocamide, Rosmarinus Officinalis (Rosemary) Oil, Triethanolamine.

Questions or comments?

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

DermacinRx[®] Penetral[™] Cream (8 fl oz bottle label)

Drug Facts

Active ingredient

Capsicum Oleoresin 0.0625% Topical Analgesic
(Containing Capsaicin 0.025%)

Purpose**Uses**

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

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Manufactured in the USA by:
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San Fernando, CA 91340
877-921-7873
For more info:
info@dermacinrx.com

List No.:310166LA
Rev:29343



NDC # 59088-310-16

DERMACINRX[®]

**Penetral[™]
Cream**

Capsaicin 0.025%

Topical use only

8 FL OZ (237mL)

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
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WATER (UNII: 059QF0KO0R)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)
ALCOHOL (UNII: 3K9958V90M)
ETHYL MENTHANE CARBO XAMIDE (UNII: 6S7S02945H)
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)
EUTERPE OLERACEA WHOLE (UNII: Y57H6218HP)
GLYCERIN (UNII: PDC6A3C0OX)
HYDROXYETHYL BEHENAMIDO PROPYL DIMONIUM CHLORIDE (UNII: 9CO8OUL4TH)
LAURYL LAURATE (UNII: GPW77G0937)
TROLAMINE (UNII: 9O3K93S3TK)
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J)
FLAX SEED (UNII: 4110YT348C)
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)

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	

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)

Establishment

Name	Address	ID/FEI	Business Operations
PureTek Corporation		785961046	manufacture(59088-310)