

**CAPSAICIN 0.025% CREAM- capsaicin 0.025% cream**  
**Puretek Corporation**

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**Capsaicin 0.025% Cream**

**Active Ingredients:**

Capsicum Oleoresin (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 a 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.

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

Store at controlled room temperature 20° to 25°C (68° to 77°F). [See USP]. Protect from light and moisture and avoid excessive heat.

## Inactive ingredient

Acrylates Copolymer, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aloe Barbadensis (Aloe Vera) Leaf Juice, Aqua (Purified Water), Arnica Montana Flower Extract, Ethyl Alcohol, Ethyl Mentane 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.

## Label

<p>Manufactured in the USA by:  <b>PureTek Corporation</b>  Panorama City, CA 91402  For questions or information  call toll-free: 877-921-7873</p> <p>List No: 22008GA  Rev: 39135</p> 	<p><b>Drug Facts</b></p> <table border="1"> <thead> <tr> <th>Active ingredient</th> <th>Purpose</th> </tr> </thead> <tbody> <tr> <td>Capsicum Oleoresin (Containing Capsaicin 0.025%)</td> <td>Topical Analgesic</td> </tr> </tbody> </table> <p><b>Uses</b>  for the temporary relief of minor aches and pains of muscles and joints associated with simple backache, arthritis, strains and sprains</p> <p><b>Warnings</b>  <b>For external use only</b></p> <ul style="list-style-type: none"> <li>• This is not a face cream. Do not apply to the face.</li> <li>• Do not use if allergic to chili peppers or if past allergic reaction to capsaicin.</li> <li>• Do not apply to wounds or damaged, broken, sunburned, chapped or irritated skin.</li> <li>• Do not bandage tightly.</li> <li>• 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 burning sensation.</li> <li>• Do not use with heating pad, hot water bottle or other source of heat. Doing so can increase risk of serious burns.</li> </ul> <p>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.</p> <p>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.</p> <p><b>Directions</b></p> <ul style="list-style-type: none"> <li>• Rotate pump's spout counter-clockwise slightly to unlock; clockwise to lock.</li> <li>• Before using on children under 18 years of age consult a physician.</li> <li>• 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.</li> <li>• Gently massage into the skin until fully absorbed.</li> <li>• Wash hands with soap and water thoroughly after each application to avoid spreading to the eyes or other sensitive mucous membranes.</li> </ul> <p><b>Other information</b> Store at controlled room temperature 20° to 25°C (68° to 77°F). [See USP]. Protect from light and moisture and avoid excessive heat.</p> <p><b>Inactive ingredient</b>  Acrylates Copolymer, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aloe Barbadensis (Aloe Vera) Leaf Juice, Aqua (Purified Water), Arnica Montana Flower Extract, Ethyl Alcohol, Ethyl Mentane 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.</p>	Active ingredient	Purpose	Capsicum Oleoresin (Containing Capsaicin 0.025%)	Topical Analgesic	<p>NDC 59088-220-08</p> <p><b>DERMACIN<sup>®</sup></b></p> <p><b>Capsaicin 0.025%  Cream</b></p> <p><b>Topical Analgesic</b></p> <p>120 g (4.23 oz)</p>
	Active ingredient	Purpose				
	Capsicum Oleoresin (Containing Capsaicin 0.025%)	Topical Analgesic				

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**PureTek Corporation**  
Panorama City, CA 91402

For questions or information  
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## CAPSAICIN 0.025% CREAM

capsaicin 0.025% cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:59088-220
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>CAPVICUM OLEORESIN</b> (UNII: UW86K581WY) (CAPVICUM OLEORESIN - UNII:UW86K581WY)	CAPVICUM OLEORESIN	0.025 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>ETHYL MENTHANE CARBOXAMIDE</b> (UNII: 6S7S02945H)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>MENTHA PIPERITA (PEPPERMINT) OIL</b> (UNII: AV092KU4JH)	
<b>ROSMARINUS OFFICINALIS (ROSEMARY) LEAF OIL</b> (UNII: 8LGU7VM393)	
<b>TRIETHANOLAMINE</b> (UNII: 9O3K93S3TK)	
<b>LAURYL LAURATE</b> (UNII: GPW77G0937)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>BUTYL ACRYLATE/METHYL METHACRYLATE/METHACRYLIC ACID COPOLYMER (18000 MW)</b> (UNII: JZ1374NL9E)	
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>MENTHYL LACTATE, (-)-</b> (UNII: 2BF9E65L7I)	
<b>ALOE BARBADENSIS LEAF JUICE</b> (UNII: ZY81Z83H0X)	
<b>AQUA</b> (UNII: 059QF0KO0R)	
<b>ARNICA MONTANA FLOWER</b> (UNII: OZ0E5Y15PZ)	
<b>ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER (60000 MPA.S)</b> (UNII: 8Z5ZAL5H3V)	
<b>LINUM USITATISSIMUM (LINSEED) SEED OIL</b> (UNII: 84XB4DV00W)	
<b>METHYL DIISOPROPYL PROPIONAMIDE</b> (UNII: 6QOP5A9489)	
<b>PPG-2 HYDROXYETHYL COCAMIDE</b> (UNII: 34N07GUJ3X)	
<b>HYDROXYETHYL BEHENAMIDOPROPYL DIMONIUM CHLORIDE</b> (UNII: 9CO8OUL4TH)	
<b>EUTERPE OLERACEA FRUIT OIL</b> (UNII: Z0W6766A2W)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59088-220-08	120 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	01/02/2025	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	01/02/2025	

**Labeler** - Puretek Corporation (785961046)

Revised: 1/2025

Puretek Corporation