

**CAPSAICIN 0.05% CREAM- capsaicin 0.05% cream**  
**Puretek Corporation**

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**Capsaicin 0.05% Cream**

**Active ingredient**

Capsicum Oleoresin (Containing Capsaicin 0.05%)

**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 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.

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 ingredients**

Aloe Barbadensis (Aloe Vera) Leaf Juice, Aqua (Purified Water), Arnica Montana (Arnica) Flower Extract, Bisabolol, C12-15 Alkyl Benzoate, C13-14 Isoparaffin, Calcium Pantothenate (Vitamin B5), Calendula Officinalis Flower Extract, Carthamus Tinctorius (Safflower) Oleosomes, Cetearyl Alcohol, Chamomilla Recutita (Matricaria) Flower Extract, Dimethicone, DL-Alpha-Tocopheryl Acetate (Vitamin E), Ginkgo Biloba (Ginkgo) Leaf Extract, Glycerin, Glyceryl Stearate, Isopropyl Myristate, Laureth-7, Lavandula Angustifolia (Lavender) Oil, Maltodextrin, Myristyl Myristate, Niacinamide (Vitamin B3), PEG-100 Stearate, Phenoxyethanol, Polyacrylamide, Pyridoxine HCl (Vitamin B6), Silica, Sodium Ascorbyl Phosphate (Vitamin C), Sodium Hyaluronate, Sodium Starch Octenylsuccinate, Zingiber Officinale (Ginger) Root Extract.

## **Label**

Manufactured in the USA by:

**PureTek Corporation**

Panorama City, CA 91402

For questions or information

call toll-free: **877-921-7873**

Manufactured in the USA by:  
**Puretek Corporation**  
 Panorama City, CA 91402  
 For questions or information  
 call toll-free: 877-921-7673

List No: 223081GA  
 Rev: 39157



<b>Drug Facts</b>	
<b>Active ingredient</b> Capsicum Oleoresin ..... (Containing Capsaicin 0.05%)	<b>Purpose</b> .....Topical Analgesic
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NDC 59088-223-08

**DERMACIN<sup>®</sup>**

**Capsaicin 0.05%  
Cream**

**Topical Analgesic**

**For external use only**

**120 g (4.23 oz)**

## CAPSAICIN 0.05% CREAM

capsaicin 0.05% cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:59088-223
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>CAPSICUM OLEORESIN</b> (UNII: UW86K581WY) (CAPSICUM OLEORESIN - UNII:UW86K581WY)	CAPSAICIN	0.5 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>CALENDULA OFFICINALIS FLOWER</b> (UNII: P0M7O4Y7YD)	
<b>CETEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	
<b>PHENOXYETHANOL</b> (UNII: H1E492ZZ3T)	
<b>ARNICA MONTANA FLOWER</b> (UNII: OZ0E5Y15PZ)	
<b>ALUMINUM STARCH OCTENYLSUCCINATE</b> (UNII: I9PJ006294)	
<b>CARTHAMUS TINCTORIUS (SAFFLOWER) OLEOSOMES</b> (UNII: 9S60Q72309)	
<b>MYRISTYL MYRISTATE</b> (UNII: 4042ZC00DY)	
<b>NIACINAMIDE</b> (UNII: 25X5118RD4)	

<b>GLYCERIN</b> (UNII: PDC6A3C0OX)
<b>PEG-100 STEARATE</b> (UNII: YD01N1999R)
<b>SODIUM ASCORBYL PHOSPHATE</b> (UNII: 836SJG51DR)
<b>GINGER</b> (UNII: C5529G5JPQ)
<b>SODIUM HYALURONATE</b> (UNII: YSE9PPT4TH)
<b>BISABOLOL</b> (UNII: 24WE03BX2T)
<b>MALTODEXTRIN</b> (UNII: 7CVR7L4A2D)
<b>AQUA</b> (UNII: 059QF0K00R)
<b>GINKGO BILOBA LEAF</b> (UNII: 19FUJ2C58T)
<b>ISOPROPYL MYRISTATE</b> (UNII: 0RE8K4LNJS)
<b>LAURETH-7</b> (UNII: Z95S6G8201)
<b>LAVANDULA ANGUSTIFOLIA (LAVENDER) OIL</b> (UNII: ZBP1YXW0H8)
<b>C13-14 ISOPARAFFIN</b> (UNII: E4F12ROE70)
<b>CALCIUM PANTOTHENATE</b> (UNII: 568ET80C3D)
<b>SILICA</b> (UNII: ETJ7Z6XBU4)
<b>CHAMOMILE</b> (UNII: FGL3685T2X)
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)
<b>.ALPHA.-TOCOPHEROL ACETATE, DL-</b> (UNII: WR1WPI7EW8)
<b>GLYCERYL STEARATE</b> (UNII: 230OU9XXE4)
<b>PYRIDOXINE HCL</b> (UNII: 68Y4CF58BV)
<b>ALOE BARBADENSIS LEAF JUICE</b> (UNII: ZY81Z83H0X)
<b>C12-15 ALKYL BENZOATE</b> (UNII: A9EJ3J61HQ)
<b>ACRYLAMIDE/SODIUM ACRYLOYLDIMETHYLAURATE COPOLYMER (120000 MPA.S AT 1%)</b> (UNII: 5F4963KLHS)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59088-223-08	120 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	01/30/2025	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	01/30/2025	

**Labeler** - Puretek Corporation (785961046)

### Establishment

Name	Address	ID/FEI	Business Operations
Puretek Corporation		785961046	manufacture(59088-223)