

CAPSAICIN 0.05% CREAM- capsaicin 0.05% cream
Puretek Corporation

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**

Drug Facts

Active ingredient
Capsaicin Cream
(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, continuously 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 Controlled Room Temperature requirements and full instructions for use.] Avoid excessive heat.

Inactive ingredients
Aloe Barbadensis (Aloe Vera) Leaf Juice, Aqua (Purified Water), Arnica Montana (Arnica) Flower Extract, Saccharol, C-12-15 Alkyl Benzoate, C12-14 Isoparaffin, Calcium Panthothenate (Vitamin B5), Calendula Officinalis Flower Extract, Carthamus Tinctorius (Safflower) Oleosomes, Cetylol, Alcohol, Chamomilla Recutita (Matricaria) Flower Extract, Dimethicone, DL-Alpha-Tocopheryl Acetate (Vitamin E), Geraniol, Ginkgo Biloba (Ginkgo) Leaf Extract, Glycine, Glycerol Stearate, Isopropyl Myristate, Laureth-7, Laureth-9, Laureth-10, Lavandula Oil, Malodolamin, 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.

NDC 59088-223-08

DERMACIN_R

**Capsaicin 0.05%
Cream**

Topical Analgesic

For external use only

120 g (4.23 oz)

Manufactured in the USA by
Puretek Corporation
Palo Alto, CA 94302
For additional information
call (800) 877-9271-7873

List No. 2230854
Rev. 09/19/10/11



CAPSAICIN 0.05% CREAM

capsaicin 0.05% cream

Product Information

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

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
CETEARYL ALCOHOL (UNII: 2DMT128M1S)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SILICA (UNII: ETJ7Z6XBU4)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
CARTHAMUS TINCTORIUS (SAFFLOWER) OLEOSOMES (UNII: 9S60Q72309)	
MYRISTYL MYRISTATE (UNII: 4042ZC00DY)	
NIACINAMIDE (UNII: 25X5118RD4)	
GLYCERIN (UNII: PDC6A3COOX)	
PEG-100 STEARATE (UNII: YD01N1999R)	
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: I9PJ006294)	
GINGER (UNII: C5529G5JPQ)	
SODIUM HYALURONATE (UNII: YSE9PPT4TH)	
BISABOLOL (UNII: 24WE03BX2T)	

MALTODEXTRIN (UNII: 7CVR7L4A2D)
AQUA (UNII: 059QF0KO0R)
GINKGO BILOBA LEAF (UNII: 19FUJ2C58T)
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)
LAURETH-7 (UNII: Z95S6G8201)
LAVANDULA ANGUSTIFOLIA (LAVENDER) OIL (UNII: ZBP1YXW0H8)
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)
CALCIUM PANTOTHENATE (UNII: 568ET80C3D)
SODIUM ASCORBYL PHOSPHATE (UNII: 836SJG51DR)
PYRIDOXINE HCL (UNII: 68Y4CF58BV)
C12-15 ALKYL BENZOATE (UNII: A9EJ3J61HQ)
ACRYLAMIDE/SODIUM ACRYLOYLDIMETHYLTAURATE COPOLYMER (120000 MPA.S AT 1%) (UNII: 5F4963KLHS)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
CHAMOMILE (UNII: FGL3685T2X)
DIMETHICONE (UNII: 92RU3N3Y1O)
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)
GLYCERYL STEARATE (UNII: 230OU9XXE4)

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)

Revised: 2/2025

Puretek Corporation