

CIRCATRIX- 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.

Circatrix™

0.05% Capsaicin

01-14-2022 - Edit marketing date from 03-01-2022 to 01-14-2022.

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, bruises, and sprains.

Warnings

For external use only

- This is not a face cream. Do not apply to the face.
- Do not use at the same time with other topical analgesics
- 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 burn.

When using this product

- Do not get into the 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

- 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.

Storage

WARNING: FLAMMABLE PRODUCT

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

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Avoid excessive heat. Do not use if package is damaged.

Inactive ingredients

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

Questions or comments?

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: **877-921-7873**

Drug Facts	
Active Ingredient	Purpose
Capsicum Oleoresin.....	Topical Analgesic
(Containing Capsaicin 0.05%)	
Uses	
For the temporary relief of minor aches and pains of muscles and joints associated with simple backache, arthritis, strains, bruises, and sprains.	
Warnings	
For external use only	
<ul style="list-style-type: none"> ■ This is not a face cream. Do not apply to the face. ■ Do not use at the same time with other topical analgesics ■ 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 burn. 	
When using this product ■ Do not get into the 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 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 the 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	
<ul style="list-style-type: none"> ■ Before using on children under 18 years of age consult a physician. ■ Apply a thin layer of the product over the 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. 	
WARNING: FLAMMABLE PRODUCT Store in a cool well ventilated area away from heat. Keep away from sparks or open flame.	
Inactive Ingredients	
Aloe Barbadensis (Aloe Vera) Leaf Juice Powder, Aqua (Purified Water), Amica Montana Flower Extract, Bisabolol, C12-15 Alkyl Benzoate, C13-14 Isoparaffin, Calcium D-Pantothenate, Calendula Officinalis Flower Extract, Carthamus Tinctorius (Safflower) Oleosomes, Cetearyl Alcohol, Chamomilla Recutita (Matricaria) Flower Extract, Dimethicone, Ginkgo Biloba Leaf Extract, Glycerin, Glyceryl Stearate, Isopropyl Myristate, Laureth-7, Lavandula Angustifolia (Lavender) Oil, Maltodextrin, Myristyl Myristate, Niacinamide, PEG-100 Stearate, Phenoxyethanol, Polyacrylamide, Pyridoxine Hydrochloride, Silicon Dioxide, Sodium Ascorbyl Phosphate, Sodium Hyaluronate, Sodium Starch Octenylsuccinate, DL- α -Tocopheryl Acetate, Zingiber Officinale (Ginger) Root Extract	

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].
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 List No. 479051AA Rev: 38358



NDC 59088-479-05

DERMACIN[®]

Circatrix[™]
 Medicated Formula

0.05% Capsaicin

Pain Relieving Cream

1 tube, 2oz. (57 g)

Use under the direction of a medical practitioner

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].
 Avoid excessive heat. Do not use if package is damaged.

Packaged for :
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 Panorama City, CA 91402
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List No. 479051AA Rev: 38357



CIRCATRIX
 capsaicin cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59088-479
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAPSIUM OLEORESIN (UNII: UW86K581WY) (CAPSIUM OLEORESIN - UNII:UW86K581WY)	CAPSAICIN	0.05 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
POLYOXYL 100 STEARATE (UNII: YD01N1999R)	
WATER (UNII: 059QF0KO0R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
LAURETH-7 (UNII: Z95S6G8201)	
CALCIUM PANTOTHENATE (UNII: 568ET80C3D)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
NIACINAMIDE (UNII: 25X5118RD4)	
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
CHAMOMILE (UNII: FGL3685T2X)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
GINKGO (UNII: 19FUJ2C58T)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
MYRISTYL MYRISTATE (UNII: 4042ZC00DY)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
OCTENYLSUCCINIC ACID (UNII: 12UZE4X73L)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
GINGER (UNII: C5529G5JPQ)	
LEVOMENOL (UNII: 24WE03BX2T)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
CARTHAMUS TINCTORIUS (SAFFLOWER) OLEOSOMES (UNII: 9S60Q72309)	
SODIUM ASCORBYL PHOSPHATE (UNII: 836SJG51DR)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
POLYACRYLAMIDE (10000 MW) (UNII: E2KR9C9V2I)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59088-479-05	57 g in 1 TUBE; Type 0: Not a Combination Product	01/14/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	01/14/2022	

Labeler - PureTek Corporation (785961046)

