

CAPSAICIN CREAM 0.1%- capsaicin cream
Pharmaceutica North America, Inc.

Active Ingredient

Capsaicin 0.1%

Purpose

Topical Analgesic

Uses

For the temporary relief of minor aches and pains of muscles and joints associated with:

- Arthritis
- Simple Backache
- Strains
- Sprains
- Bruises

Warnings

For external use only: TEST FIRST ON SMALL AREA OF SKIN.

When using this product:

Due not use

- Do not apply to wounds, damaged, broken or irritated skin
- if you are allergic to capssicum or chili peppers

When using this product

- use only as directed
- Do not apply to wounds, damaged, broken or irritated skin
- Do not use if you are allergic to capssicum or chili peppers
- Avoid contact with the eyes or mucous membranes
- A slight burning sensation may occur upon application, but generally disappears after several days of use
- If severe burning occurs, discontinue use
- Do not expose the treated area to heat or direct sunlight
- Do not bandage
- Do not use with heating pad

Stop Use and Ask Doctor if:

- Condition worsens
- Symptoms persist for more than 7 days or clear up and occur again within a few days
- Redness is present
- irritation develops

Keep Out of the Reach of Children. If swallowed, get medical help or contact a

Poison Control Center (1-800-222-1222) right away.

Directions

• **do not take more than directed (see overdose warning)
adults and children over 18 years and over:**

- apply to affected area
- massage into the painful area until thoroughly absorbed
- repeat as necessary but not more than 3 to 4 times daily
- WASH HANDS WITH SOAP AND WATER AFTER APPLYING

children under 18 years and younger:ask a doctor

Other information

- store at room temperature 15° - 30°C (59 - 86°F)

Inactive Ingredients

Aloe barbadensis leaf juice, Cetostearyl alcohol, Ethylparaben, Glycerin, Glyceryl monostearate, Mineral Oil, Petrolatum, Polyoxyethylene lauryl ether, Purified Water, stearic acid.

Questions or comments? (888)788-6472

Product label



CAPSAICIN CREAM 0.1%

capsaicin cream

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:45861-074 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------------|
| CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM) | CAPSAICIN | 0.1 g in 100 g |

Inactive Ingredients

| Ingredient Name | Strength |
|-----------------------------------|----------|
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| ETHYLPARABEN (UNII: 14255EXE39) | |

| | |
|---|--|
| MINERAL OIL (UNII: T5L8T28FGP) | |
| STEARYL ALCOHOL (UNII: 2KR89I4H1Y) | |
| WATER (UNII: 059QF0KO0R) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4) | |
| PETROLATUM (UNII: 4T6H12BN9U) | |
| LAURETH-15 (UNII: 002FR4N8OV) | |
| CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:45861-074-04 | 1 in 1 BOX | 02/01/2025 | |
| 1 | | 42.5 g in 1 TUBE; Type 0: Not a Combination Product | | |

Marketing Information

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

Labeler - Pharmaceutica North America, Inc. (962739699)

Revised: 3/2025

Pharmaceutica North America, Inc.