# CAPSAICIN TOPICAL ANALGESIC- capsaicin cream AvPAK

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Capsaicin Cream 0.075%

**Drug Facts** 

## **Active ingredient**

Capsaicin 0.075%

#### **Purpose**

**Topical Analgesic** 

#### Uses

temporarily relieves minor aches and pains of muscles and joints due to:

- simple backache
- arthritis
- strains
- sprains

# Warnings

# For external use only

Read all warnings and directions before use. TEST FIRST ON SMALL AREA OF SKIN.

#### Do not use

- on wounds or damaged skin
- if you are allergic to capsicum or chili peppers
- with heating pad

# When using this product

- you may experience a burning sensation. The intensity of this reaction varies among individuals and may be severe. With regular use, this sensation generally disappears after several days.
- avoid contact with eyes, lips, nose and mucous membranes
- do not tightly wrap or bandage the treated area
- do not apply heat to the treated area immediately before or after use

# Stop and ask a doctor if

- condition worsens or does not improve after regular use
- severe burning persists
- redness or blistering occurs

**Keep out of reach of children**. If swallowed, get medical help or contact a Poison Control Center immediately.

#### **Directions**

Adults and children 18 years of age and older:

- apply a thin film of cream to affected area and gently rub in until fully absorbed
- unless treating hands, wash hands thoroughly with soap and water immediately after application
- for best results, apply 3 to 4 times daily.

Children under 18 years: ask a doctor

#### Other information

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

### **Inactive ingredients**

Aloe barbadensis leaf extract, cetyl alcohol, glyceryl stearate SE, mineral oil, PEG-100 stearate, peppermint oil, phenoxyethanol, propylene glycol, purified water, stearyl alcohol, white petrolatum, xanthan gum

## Questions or comments?

1-855-361-3993

Manufactured for:

AvKARE, Pulaski, TN 38478

www.avkare.com

AV 06/22

# PRINCIPAL DISPLAY PANEL - 57 g Tube Carton

# Capsaicin Cream 0.075 %

**External Analgesic Cream** 

Penetrating Pain Relief



Uses temporarily relieves minor aches and pains of muscles and joints due to: ■ simple backache ■ arthritis ■ strains ■ sprains

Warnings For external use only. Read all warnings and directions before use. Test first on a small area of skin. Do not use ■ on wounds or damaged skin ■ if you are allergic to capsicum or chili peppers with heating pad When using this product you may experience a burning sensation. The intensity of this reaction varies among individuals and may be severe. With regular use, this sensation-generally-disappears after several-days. avoid contact with the eyes, lips, nose and mucous membranes do not tightly wrap or bandage the treatment area do not apply heat, or direct sunlight to the treated area immediately before or after use Stop use and ask a doctor if condition worsens or does not improve after regular use ■ severe burning persists redness or blistering occurs Keep out of the reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions Adults and children 18 years of age and older: ■ apply a thin film of cream to affected area and gently rub in until fully absorbed ■ unless treating hands, wash hands thoroughly with soap and water immediately after application ■ for best results, apply 3 to 4 times daily. Children under 18 years: ask a doctor.

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#### Questions? Comments?

1–855-361–3993 Manufactured for: AvKARE, Pulaski, TN 38478 www.avkare.com AV 06/22



#### CAPSAICIN TOPICAL ANALGESIC

capsaicin cream

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Product Type HUMAN OTC DRUG Item Code (Source) NDC:50268-196

Route of Administration TOPICAL

# **Active Ingredient/Active Moiety**

| Ingredient Name  | <b>Basis of Strength</b> | Strength       |
|--|--------------------------|----------------|
| CAPSAICIN (UNII: S07044R1ZM) (CAPSAICIN - UNII:S07044R1ZM) | CAPSAICIN                | 0.75 mg in 1 g |

| Inactive Ingredients                    |          |  |  |
|---|----------|--|--|
| Ingredient Name                         | Strength |  |  |
| PEPPERMINT OIL (UNII: AV092KU4JH)       |          |  |  |
| MINERAL OIL (UNII: T5L8T28FGP)          |          |  |  |
| ALOE VERA LEAF (UNII: ZY81Z83H0X)       |          |  |  |
| STEARYL ALCOHOL (UNII: 2KR89I4H1Y)      |          |  |  |
| XANTHAN GUM (UNII: TTV12P4NEE)          |          |  |  |
| GLYCERYL STEARATE SE (UNII: FCZ5MH785I) |          |  |  |
| PHENOXYETHANOL (UNII: HIE492ZZ3T)       |          |  |  |
| CETYL ALCOHOL (UNII: 936JST6JCN)        |          |  |  |
| PEG-100 STEARATE (UNII: YD01N1999R)     |          |  |  |
| PETROLATUM (UNII: 4T6H12BN9U)           |          |  |  |
| WATER (UNII: 059QF0KO0R)                |          |  |  |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)     |          |  |  |

| Product Characteristics |       |              |
|-------------------------|-------|--------------|
| Color                   | white | Score        |
| Shape                   |       | Size         |
| Flavor                  |       | Imprint Code |
| Contains                |       |              |

| ı | Packaging            |   |                         |                       |  |
|---|----------------------|---|-------------------------|-----------------------|--|
|   | # Item Code          | Package Description                               | Marketing Start<br>Date | Marketing End<br>Date |  |
|   | NDC:50268-196-<br>57 | 1 in 1 CARTON                                     | 12/08/2022              |                       |  |
|   | L                    | 57 g in 1 TUBE; Type 0: Not a Combination Product |                         |                       |  |

| Marketing Information |   |                         |                       |  |
|-----------------------|---|-------------------------|-----------------------|--|
| Marketing<br>Category | Application Number or Monograph<br>Citation | Marketing Start<br>Date | Marketing End<br>Date |  |
| OTC Monograph Drug    | M017  | 12/08/2022              |                       |  |
|                       |   |                         |                       |  |

# **Labeler -** AvPAK (832926666)

Revised: 3/2024 AvPAK