

## **CAPSAICIN EXTERNAL ANALGESIC- capsaicin cream AvPAK**

*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.*

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### **Capsaicin Cream 0,025%**

#### **Drug Facts**

#### **Active ingredient**

Capsaicin 0.025%

#### **Purpose**

External 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 the 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 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 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° - 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](http://www.avkare.com)

AV 06/22

**PRINCIPAL DISPLAY PANEL - 60 g Tube Carton**

NDC 50268-195-60

# Capsaicin Cream **0.025 %**

**External Analgesic Cream**



Penetrating Pain Relief

NET WT. 2.1 OZ. (60 g)

**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.

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

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## CAPSAICIN EXTERNAL ANALGESIC

capsaicin cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:50268-195
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>CAPSAICIN</b> (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)	CAPSAICIN	0.25 mg in 1 g

## Inactive Ingredients

Ingredient Name	Strength
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PETROLATUM (UNII: 4T6H12BN9U)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
XANTHAN GUM (UNII: TTV12P4NEE)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
MINERAL OIL (UNII: T5L8T28FGP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
GLYCERYL STEARATE/PEG-100 STEARATE (UNII: RD25J5V947)	

## Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50268-195-60	1 in 1 CARTON	12/08/2022	
1		60 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 not final	part348	12/08/2022	

**Labeler** - AvPAK (832926666)

Revised: 12/2022

AvPAK