

CAPSAICIN- capsaicin cream **AvPAK**

Capsaicin Cream 0.1%

Active Ingredient: Capsaicin 0.1%

Purpose: Topical Analgesic

Uses: Provides penetrating pain relief. 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.

Do not use:

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

When using this produce:

- you may experience a burning sensation The intensity of this reaction varies among individuals and may be severe. With regular use, the 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 reach of children. If product is 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)

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? Comments?

1-855-361-3993

Manufactured for:

AvKARE, Pulaski, TN 38478

www.avkare.com

AV 06/22

Packaging

NDC 50268-197-56

Capsaicin Cream 0.1%

External Analgesic Cream

AVKARE®
NET WT. 2 OZ. (56.6 g)

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 capsaicin 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

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CAPSAICIN

capsaicin cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50268-197
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAPSAICIN (UNII: S07O44R1Z M) (CAPSAICIN - UNII:S07O44R1Z M)	CAPSAICIN	0.001 g in 1 g

Inactive Ingredients

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

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50268-197-56	1 in 1 CARTON	12/08/2022	
1		56.6 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	12/08/2022	

Labeler - AvPAK (832926666)