#### CAPSAICIN EXTERNAL ANALGESIC- capsaicin cream AvPAK

-----

#### 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

AV 06/22

# PRINCIPAL DISPLAY PANEL - 60 g Tube Carton



# 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.

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



#### CAPSAICIN EXTERNAL ANALGESIC capsaicin cream **Product Information Product Type** HUMAN OTC DRUG Item Code (Source) NDC:50268-195 **Route of Administration** TOPICAL **Active Ingredient/Active Moiety Basis of Strength** Strength Ingredient Name CAPSAICIN (UNII: S07044R1ZM) (CAPSAICIN - UNII:S07044R1ZM) CAPSAICIN 0.25 mg in 1 g

GLYCERYL STEARATE SE (UNII: FCZ 5MH785I)       Image: Stear S		dients				
CETYL ALCOHOL (UNII: 936/576/CN)       Image: Start of the start of t	Ingredient Name					
PHENOXYETHANOL (UNII: HIE492Z 2 3T) GLYCERYL STEARATE/PEG-100 STEARATE (UNII: RD25J5V947) PETROLATUM (UNII: 4T6H12BN9U) STEARYL ALCOHOL (UNII: 2K889I4H1Y) XANTHAN GUM (UNII: TTV12P4NEE) PEPPERMINT OIL (UNII: AV092KU4JH) ALOE VERA LEAF (UNII: Z 781Z 83H0X) MINERAL OIL (UNII: 518728FGP) PROPYLENE GLYCOL (UNII: 6DC9Q167V3) WATER (UNII: 059QF0KOOR) PROPYLENE GLYCOL (UNII: 6DC9Q167V3) WATER (UNII: 059QF0KOOR) Product Characteristics Color white Score Shape Size Flavor Size Flavor Imprint Code Contains Marketing End Date Marketing End Date Packaging # Item Code Package Description Marketing Start Marketing End Date Marketing Information Marketing Marketing End Date Marketing End Marketing End Marketing End Marketing Marketing End Date Marketing End Date Marketing End Marketing Marketing End Date Marketing En						
GLYCERYL STEARATE/PEG-100 STEARATE (UNII: RD25/5V947) PETROLATUM (UNII: 4T6H12BN9U) STEARYL ALCOHOL (UNII: 2K8914H1Y) XANTHAN GUM (UNII: TTV12P4NEE) PEPPERMINT OLL (UNII: X092KU4JH) ALOE VERA LEAF (UNII: ZY81Z83H0X) MINERAL OIL (UNII: TSL8T28FGP) PROPYLENE GLYCOL (UNII: 6DC9Q167V3) WATER (UNII: 059QF0KOOR) PROPYLENE GLYCOL (UNII: 6DC9Q167V3) PROPYLENE GLYCOL		· _ · _ ·				
PETROLATUM (UNII: 4T6H12BN9U) STEARYL ALCOHOL (UNII: 2KR89I4H1Y) KANTHAN GUM (UNII: TTV12P4NEE) PEPPERMINT OIL (UNII: TV12P4NEE) PEPPERMINT OIL (UNII: TV12P4NEE) PEPPERMINT OIL (UNII: TS12B3H0X) MINERAL OIL (UNII: T5L8T28FGP) PROPYLENE GLYCOL (UNII: 6DC9Q167V3) WATER (UNII: 059QF0K00R) PROPYLENE GLYCOL (UNII: 6DC9Q167V3) PROPYLENE GLYCOL (UNII: 6DC9Q167V3) PR						
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)			<b>EARATE</b> (UNII: RD2	25J5V947)		
AANTHAN GUM (UNII: TTV12P4NEE)       Image: State						
PEPPERMINT OIL (UNII: AV092KU4)H) ALOE VERA LEAF (UNII: ZYB1Z 83H0X) MINERAL OIL (UNII: T5L8T28FGP) PROPYLENE GLYCOL (UNII: 6DC9Q167V3) WATER (UNII: 059QF0KO0R) Product Characteristics Color v v v v v v v v v v v v v v v v v v v			11Y)			
ALOE VERA LEAF (UNII: ZYB1283H0X) MINERAL OIL (UNII: T5L8T28FGP) PROPYLENE GLYCOL (UNII: 6DC9Q167V3) WATER (UNII: 059QF0K00R) Product Characteristics Color white Score Shape Size						
MINERAL OIL (UNII: T5L8T28FGP) PROPYLENE GLYCOL (UNII: 6DC9Q167V3) WATER (UNII: 059QF0KOOR) Product Characteristics Color white Score		-				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3) WATER (UNII: 059QF0K00R) Product Characteristics Color white Score Shape value			)X)			
water (UNII: 059QF0KOOR)  Product Characteristics Color white Score Shape Size Flavor Contains  Size Imprint Code Imprint Code Contains  Marketing Start Date Marketing End Date  Marketing I  Size I in 1 CARTON I						
Product Characteristics       white       Score         Color       white       Score       ite         Shape       Size       ite       ite         Flavor       Imprint Code       ite       ite         Contains       Imprint Code       ite       ite         Packaging       Marketing Start       Marketing End Date         Model       Package Description       Marketing Start       Marketing End Date         1       NDC:50268-195-       1 in 1 CARTON       12/08/2022       ite         1       MDC:50268-195-       1 in 1 CARTON       12/08/2022       ite         1       Marketing Information       Marketing Start       Marketing End Date			107V3)			
NDC:50268-195- 1     1 in 1 CARTON Product     Marketing Start 60 g in 1 TUBE; Type 0: Not a Combination Product     Marketing Start 12/08/2022     Marketing Start Date     Marketing End Date		FUNUUR)				
Color       white       Score       Size						
Color       white       Score       Size						
Shape       Size		acteristics				
Imprint Cole   Imprint Cole   Imprint Cole   Item Code   Package Description   Marketing Start Date Marketing End Date   1 NDC:50268-195- 60 1 in 1 CARTON 12/08/2022   1 In 1 CARTON 12/08/2022   1 Marketing End Date	Color		white	Score		
Interview of the second secon	Shape			Size		
Packaging         #       Item Code       Package Description       Marketing Start Date       Marketing End Date         1       NDC:50268-195- 60       1 in 1 CARTON       12/08/2022       12/08/2022         1       60 g in 1 TUBE; Type 0: Not a Combination Product       12/08/2022       1       1         Marketing End Date         Marketing Category         Marketing Start Date	Flavor			Imprint Code		
#       Item Code       Package Description       Marketing Start Date       Marketing End Date         1       NDC:50268-195- 60       1 in 1 CARTON       12/08/2022       12/08/2022         1       60 g in 1 TUBE; Type 0: Not a Combination Product       Image: Comparison of the combination of the combinatin of the combinatin of the combination of th	Contains					
#       Item Code       Package Description       Marketing Start Date       Marketing End Date         1       NDC:50268-195- 60       1 in 1 CARTON       12/08/2022       12/08/2022         1       60 g in 1 TUBE; Type 0: Not a Combination Product       Image: Comparison of the combination of the combinatin of the combinatin of the combination of th						
#       Item Code       Package Description       Marketing Start Date       Marketing End Date         1       NDC:50268-195- 60       1 in 1 CARTON       12/08/2022       12/08/2022         1       60 g in 1 TUBE; Type 0: Not a Combination Product       Image: Comparison of the combination of the combinatin of the combinatin of the combination of th						
#       Item Code       Package Description       Date       Date         1       NDC:50268-195- 60       1 in 1 CARTON       12/08/2022       1         1       60 g in 1 TUBE; Type 0: Not a Combination Product       12/08/2022       1         Marketing Information       Marketing Start       Marketing End Date         Marketing Category       Application Number or Monograph Citation       Marketing Start Date       Marketing End Date	Packaging					
Image: Second	# Item Code	Package Description			-	-
Product       Product         Marketing Category       Application Number or Monograph Citation       Marketing Start Date       Marketing End Date		1 in 1 CARTON			12/08/2022	
Marketing CategoryApplication Number or Monograph CitationMarketing Start DateMarketing End Date	1					
Marketing CategoryApplication Number or Monograph CitationMarketing Start DateMarketing End Date						
Marketing CategoryApplication Number or Monograph CitationMarketing Start DateMarketing End Date	Marketing	Informatio	on			
	•		on Number or M	lonograph	-	-
			CILATION			

Labeler - AvPAK (832926666)

Revised: 3/2024

AvPAK