

**CAPSAICIN- capsaicin cream
SA3, LLC**

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.

Capsaicin Cream

CAPSAICIN - Capsaicin 0.025% Cream

SA3, LLC

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Capsaicin 0.025% Cream

Drug Facts

Active ingredient

Capsaicin 0.025%

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

- Apply to wounds or damaged skin
- Bandage tightly
- If you are allergic to capsicum or chili peppers

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 if symptoms persist for more than 7 days or clear up and occur again within a few days
- Severe burning persists or blistering occurs

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center immediately. If pregnant or breast-feeding, ask a health professional before use.

Directions

Adults and children 2 years of age and older:

Apply to affected area not more than 3 to 4 times daily. Wash hands thoroughly with soap and water immediately after application.

Children under 2 years: consult a doctor

Other information

Store at room temperature 15°-30°C (59°-86°F). Protect the product from excessive heat and direct sun.

Inactive ingredients

Aqua (Deionized Water), Arnica Montana Flower Extract, Boswellia Serrata Extract, Cetearyl Alcohol, Chondroitin Sulfate, Ethylhexylglycerin, Glucosamine Sulfate, Glycerin, Glyceryl Stearate, C13-14 Isoparaffin, Isostearyl Palmitate, Laureth-7, Methylsufonylmethane (MSM), PEG-100 Stearate, Phenoxyethanol, Polyacrylamide, Propylene Glycol, Sodium Polyacrylate, Stearic Acid, and Triethanolamine

PRINCIPAL DISPLAY PANEL

Capsaicin 0.025% cream

NDC 69420-6025-5

50 grams

SA3, LLC

Drug Facts		Capsaicin 0.025% Cream Topical Analgesic NDC: 69420-6025-5 50 gram (1.76 OZ)	Drug Facts (continued)	
Active ingredient Capsaicin 0.025%	Purpose Topical Analgesic		Directions: ■ Adults and children 2 years of age and older: Apply to affected area not more than 3 to 4 times daily. ■ Children under 2 years of age: consult a doctor.	
Uses: ■ For the temporary relief of minor aches and pains of muscles and joints, associated with arthritis, strains, bruises, and sprains.			Inactive ingredients: Aqua (Deionized Water), Arnica Montana Flower Extract, Boswellia Serrata Extract, Cetearyl Alcohol, Chondroitin Sulfate, Ethylhexylglycerin, Glucosamine Sulfate, Glycerin, Glyceryl Stearate, C13-14 Isoparaffin, Isostearyl Palmitate, Laureth-7, Methylsulfonylmethane (MSM), PEG-100 Stearate, Phenoxyethanol, Polyacrylamide, Propylene Glycol, Sodium Polyacrylate, Stearic Acid, Triethanolamine.	
Warnings: For external use only			Other information: ■ Protect the product in this container from excessive heat and direct sun.	
Do not ■ apply to wounds or damaged skin. ■ bandage tightly.			Questions? (888) 495-6078	
When using this product ■ Avoid contact with the eyes.				
Stop use and ask a doctor if ■ condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days.				
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. If pregnant or breast-feeding , ask a health professional before use ▶				
Manufactured for: SA3, LLC 2317 Cotner Avenue, Los Angeles, CA 90064		SA3, LLC 3 69420 60255 4		

PRINCIPAL DISPLAY PANEL

Capsaicin 0.025% cream

NDC 69420-6025-1

120 grams

SA3, LLC

Capsaicin 0.025% Cream

120 gram (4.2 OZ)

NDC: 69420-6025-1



Drug Facts		Drug Facts (continued)
Active ingredient Capsaicin 0.025%.....	Purpose Topical Analgesic	Directions: <ul style="list-style-type: none"> Adults and children 2 years of age and older: Apply to affected area not more than 3 to 4 times daily. Children under 2 years of age: consult a doctor.
Uses: <ul style="list-style-type: none"> For the temporary relief of minor aches and pains of muscles and joints, associated with arthritis, strains, bruises, and sprains. 		
Warnings: For external use only		Inactive ingredients: Aqua (Deionized Water), Arnica Montana Flower Extract, Boswellia Serrata Extract, Cetearyl Alcohol, Chondroitin Sulfate, Ethylhexylglycerin, Glucosamine Sulfate, Glycerin, Glyceryl Stearate, C13-14 Isoparaffin, Isostearyl Palmitate, Laureth-7, Methylsulfonylmethane (MSM), PEG-100 Stearate, Phenoxyethanol, Polyacrylamide, Propylene Glycol, Sodium Polyacrylate, Stearic Acid, Triethanolamine.
Do not <ul style="list-style-type: none"> apply to wounds or damaged skin. bandage tightly. 		
When using this product <ul style="list-style-type: none"> Avoid contact with the eyes. 		
Stop use and ask a doctor if <ul style="list-style-type: none"> condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days. 		Other information: <ul style="list-style-type: none"> Protect the product in this container from excessive heat and direct sun.
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. If pregnant or breast-feeding , ask a health professional before use		
		Questions? (888) 495-6078

Manufactured for: SA3, LLC
2317 Cotner Avenue, Los Angeles, CA 90064



External Analgesic

Rev 04/22

CAPSAICIN

capsaicin cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69420-6025
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)	CAPSAICIN	0.025 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
INDIAN FRANKINCENSE (UNII: 4PW41QCO2M)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLUCOSAMINE SULFATE (UNII: 1FW7VLR731)	

GLYCERIN (UNII: PDC6A3C0OX)
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)
ISOSTEARYL PALMITATE (UNII: 9EHU0R7ER1)
LAURETH-7 (UNII: Z95S6G8201)
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)
PEG-100 STEARATE (UNII: YD01N1999R)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
STEARIC ACID (UNII: 4ELV7Z65AP)
TROLAMINE (UNII: 9O3K93S3TK)
CHONDROITIN SULFATE (BOVINE) (UNII: 6IC1M3OG5Z)
POLYACRYLAMIDE (10000 MW) (UNII: E2KR9C9V2I)
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JNI2J)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69420-6025-5	50 g in 1 TUBE; Type 0: Not a Combination Product	06/11/2021	
2	NDC:69420-6025-1	120 g in 1 TUBE; Type 0: Not a Combination Product	06/11/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	06/11/2021	

Labeler - SA3, LLC (079627454)