

CAPSAICIN- capsaicin cream
Alexso, Inc

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

Alexso, Inc.

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Capsaicin 0.025% Cream

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

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 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

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

Capsaicin 0.025% cream

NDC 50488-1025-1

120 grams

Capsaicin 0.025% cream

NDC 50488-1025-5

50 grams

Capsaicin 0.025% cream

NDC 50488-1025-2

25 grams

Alexso, Inc

PRINCIPAL DISPLAY PANEL

NDC 50488-1025-1

Capsaicin 0.025% Cream

120 grams

NDC: 50488-1025-1	Drug Facts	Drug Facts (continued)
	<i>Active ingredient</i> Capsaicin 0.025%.....	<i>Purpose</i> External Analgesic
Capsaicin 0.025% Cream 120 grams	Uses Temporarily relieves minor aches and pains of muscles and joints due to: • simple backache • arthritis • strains • sprains	Directions adults and children 18 years 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
	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	Other Information - Store at 20-25°C (68-77°F); excursions permitted to 15-30°C (59-86°F). See USP Controlled Room Temperature.
	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	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, Methylsulfonylethane (MSM), PEG-100 Stearate, Phenoxyethanol, Polyacrylamide, Propylene Glycol, Sodium Polyacrylate, Stearic Acid, Triethanolamine.
	Stop use and ask a doctor if • condition worsens or does not improve after regular use • severe burning persists or blistering occurs	Keep out of the reach of children. If swallowed, get medical help or contact a Poison Control Center right away.
Manufactured for: Alexso, Inc. 2317 Cotner Avenue Los Angeles, CA 90064 Tel: 888.495.6078		 0 50488 10251 2
		External Analgesic

PRINCIPAL DISPLAY PANEL

NDC 50488-1025-5

Capsaicin 0.025% Cream

50 grams

Drug Facts		Drug Facts (continued)	
Active ingredient Capsaicin 0.025%.....	Purpose External Analgesic	Directions adults and children 18 years 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	
Uses Temporarily relieves minor aches and pains of muscles and joints due to: • simple backache • arthritis • strains • sprains		Other Information - Store at 20-25°C (68-77°F); excursions permitted to 15-30°C (59-86°F). See USP Controlled Room Temperature.	
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		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, Triethanolamine.	
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		Keep out of the reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
Stop use and ask a doctor if • condition worsens or does not improve after regular use • severe burning persists or blistering occurs		Manufactured for: Alexso, Inc. 2317 Cotner Avenue Los Angeles, CA 90064 Tel: 888.495.6078	
			

Capsaicin 0.025% Cream
50 grams
NDC: 50488-1025-5

PRINCIPAL DISPLAY PANEL

NDC 50488-1025-2
Capsaicin 0.025% Cream
25 grams



CAPSAICIN

capsaicin cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50488-1025
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)
CHONDROITIN SULFATE (BOVINE) (UNII: 6IC1M3OG5Z)
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)
GLUCOSAMINE SULFATE (UNII: 1FW7WLR731)
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)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50488-1025-1	1 in 1 CARTON	10/01/2018	
1		120 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:50488-1025-5	1 in 1 CARTON	10/01/2018	
2		50 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:50488-1025-2	1 in 1 CARTON	10/01/2018	
3		25 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	10/01/2018	

Labeler - Alexso, Inc (963338061)