

CAPSAICIN- capsaicin cream
Alexso, Inc

Capsaicin Cream

CAPSAICIN - Capsaicin 0.025% 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 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

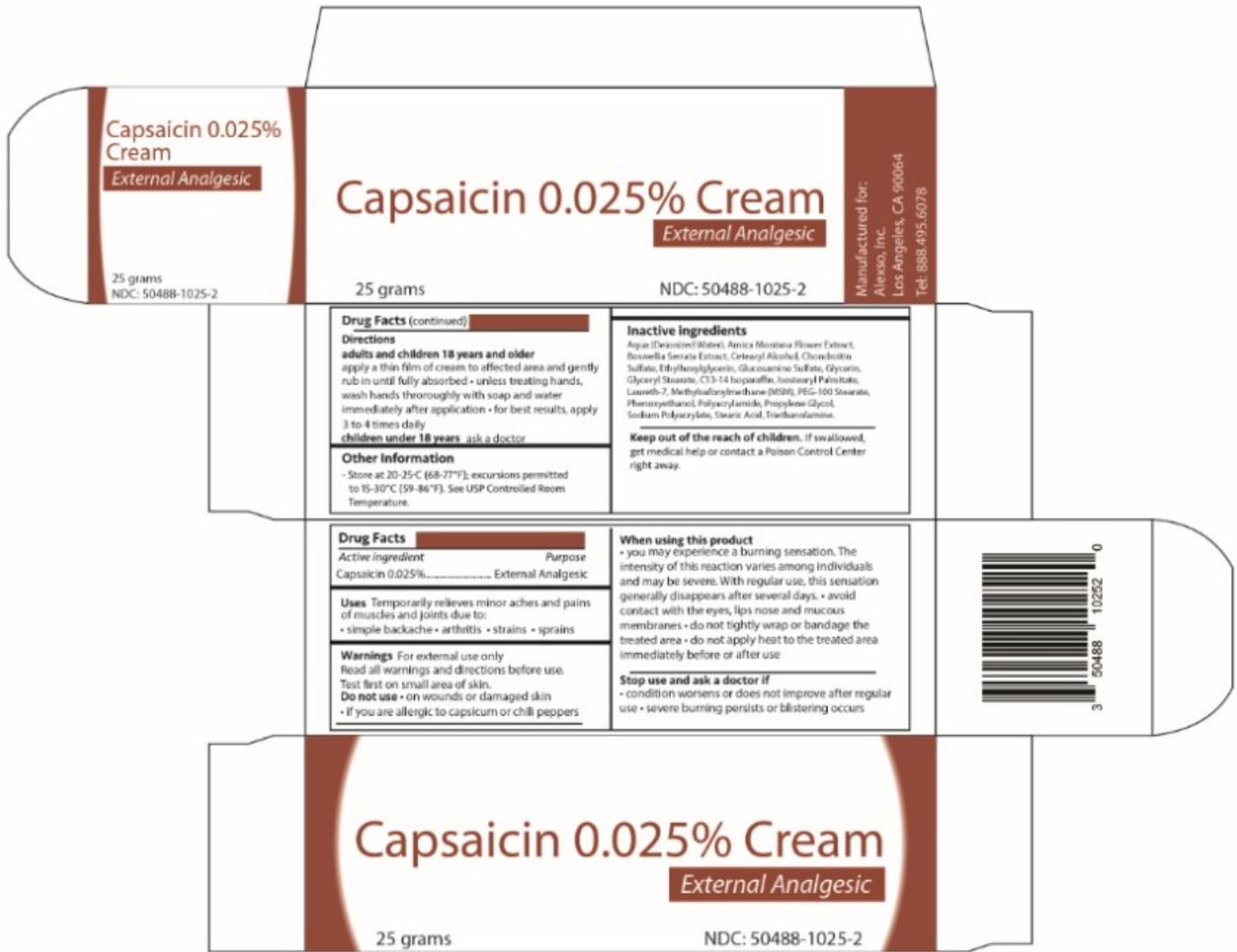
50 grams

Drug Facts		Drug Facts (continued)	
<i>Active ingredient</i>	<i>Purpose</i>	Directions	
Capsaicin 0.025%.....	External Analgesic	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	
Uses Temporarily relieves minor aches and pains of muscles and joints due to: • simple backache • arthritis • strains • sprains		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.		Other Information	
Do not use • on wounds or damaged skin • if you are allergic to capsicum or chili peppers		- 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, Methylsulfonylmethane (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	

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 Drug	M017	10/01/2018	

Labeler - Alexso, Inc (963338061)