# CAPSAICIN 0.075 PERCENT- 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.

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## Capsaicin 0\_075 Percent Cream

Capsaicin 0.075% Cream

#### **Drug Facts**

#### **Active ingredient**

Capsaicin 0.075%

#### **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

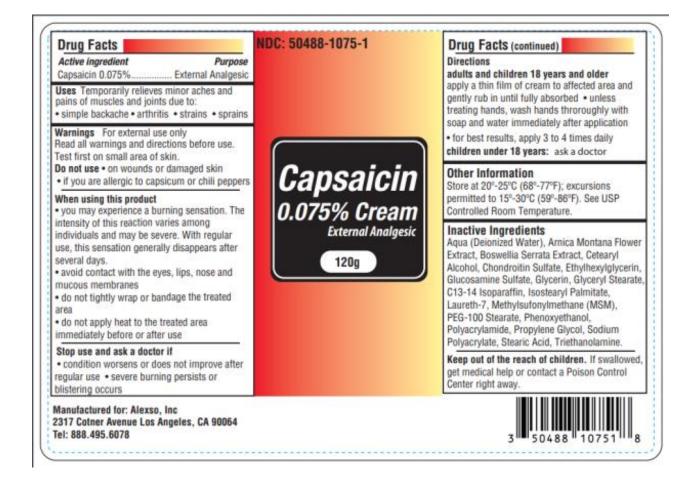
#### PRINCIPAL DISPLAY PANEL

Capsaicin 0.075% Cream

NDC 50488-1075-6

120 grams

Alexso, Inc



#### **CAPSAICIN 0.075 PERCENT**

capsaicin cream

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:50488-1075

Route of Administration TOPICAL

#### **Active Ingredient/Active Moiety**

Ingredient Name

CAPSAICIN (UNII: S07044R1ZM) (CAPSAICIN - UNII:S07044R1ZM)

Basis of Strength

CAPSAICIN

0.075 g in 100 g

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)			
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)			
BOSWELLIA SERRATA WHOLE (UNII: X7B7P649WQ)			
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)			
CHONDROITIN SULFATE (BOVINE) (UNII: 6IC1M3OG5Z)			
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)			
GLUCOSAMINE SULFATE (UNII: 1FW7WLR731)			
GLYCERIN (UNII: PDC6A3C0OX)			

GLYCERYL MONOSTEARATE (UNII: 2300U9XXE4)	
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)	
POLYACRYLAMIDE (10000 MW) (UNII: E2KR9C9V2I)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JNI2J)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TROLAMINE (UNII: 903K93S3TK)	

P	ackaging	aging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:50488- 1075-6	120 g in 1 BOTTLE; Type 0: Not a Combination Product	12/08/2021		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part348	12/08/2021		
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## **Labeler -** Alexso, Inc (963338061)

Revised: 12/2021 Alexso, Inc