

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.

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

Drug Facts

Active ingredient **Purpose**
Capsaicin 0.075%..... 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
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• 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

Manufactured for: Alexso, Inc
2317 Cotner Avenue Los Angeles, CA 90064
Tel: 888.495.6078

NDC: 50488-1075-1

Capsaicin
0.075% Cream
External Analgesic

120g

Drug Facts (continued)

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

Other Information
Store at 20°-25°C (68°-77°F); excursions permitted to 15°-30°C (59°-86°F). See USP Controlled Room Temperature.

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.

Keep out of the reach of children. If swallowed, get medical help or contact a Poison Control Center right away.


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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	Basis of Strength	Strength
CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)	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: 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)	
POLYACRYLAMIDE (10000 MW) (UNII: E2KR9C9V2I)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JN12J)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TROLAMINE (UNII: 9O3K93S3TK)	

Packaging

#	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	

Labeler - Alexso, Inc (963338061)

Revised: 12/2021

Alexso, Inc