CAPSAICIN 0.1 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 Cream

CAPSAICIN - Capsaicin 0.1% Cream

Alexso, Inc.

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Capsaicin 0.1% Cream

Drug Facts

Active ingredient

Capsaicin 0.1%

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 0.1% Cream

NDC 50488-1060-6

60 grams

Drug Facts	Drug Facts (continued)		4
Active ingredient Purpose Capsaicin 0.1% External Analgesic	Directions adults and children 18 years and older	ar	1060-6
Uses Temporarily relieves minor aches and pains of muscles and joints due to: • simple backache • arthritis • strains • sprains	apply a thin film of cream to affected area and gently rub in until fully absorbed • unless treating hands, wash hands throroughly with soap and water immediately after application • for best results, apply	Cre	50488-
Warnings For external use only Read all warnings and directions before use.	3 to 4 times daily children under 18 years ask a doctor		NDC.
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	1 9/ enc)	Z
 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 	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	psaicin 0. ^{High Pot}	arame
regular use • severe burning persists or blistering occurs	right away. Manufactured for: Alexso, Inc. 2317 Cotner Avenue Los Angeles, CA 90064 Tel: 888.495.6078	G	60 ar

CAPSAICIN 0.1 PERCENT

capsaicin cream

capsaicin cream					
Product Information					
Product Type	HUMAN OTC DRUG	ltem Code	(Source)	NDC:	50488-1060
Route of Administration	TOPICAL				
Active Ingredient/Active	Moiety				
Ingred	ient Name		Basis of Stren	gth	Strength
CAPSAICIN (UNII: S07044R1ZM) (0	CAPSAICIN - UNII:S07044R1	LZM)	CAPSAICIN		0.1 g in 100 g
Inactive Ingredients					
	Ingredient Name				Strength
STEARIC ACID (UNII: 4ELV7Z65AP)				
TROLAMINE (UNII: 903K93S3TK)					
CHONDROITIN SULFATE (BOVIN	E) (UNII: 6IC1M3OG5Z)				
POLYACRYLAMIDE (10000 MW)	(UNII: E2KR9C9V2I)				

WATED (LINUE 0500	ENVO	וסר				
		WER (UNII: OZOE5Y15PZ)				
		(UNII: 4PW41QCO2M)				
		L (UNII: 2DMT128M1S)				
ETHYLHEXYLGLYC		, , , , , , , , , , , , , , , , , , ,				
		E (UNII: 1FW7WLR731)				
GLYCERIN (UNII: PE						
•		RATE (UNII: 2300U9XXE4)				
C13-14 ISOPARAF						
		E (UNII: 9EHU0R7ER1)				
LAURETH-7 (UNII: Z						
DIMETHYL SULFO		· ·				
PEG-100 STEARAT						
PHENOXYETHANO	•	,				
PROPILENE GLIC	UL (U	NII: 6DC9Q167V3)				
Packaging	OL (U	NII: 6DC9Q167V3)				
	OL (U	Package Description	N	1arketing Start Date	М	arketing End Date
Packaging		Package Description in 1 BOTTLE; Type 0: Not a Combination			М	
Packaging # Item Code	60 g	Package Description in 1 BOTTLE; Type 0: Not a Combination		Date	М	
Packaging # Item Code	60 g Prod	Package Description in 1 BOTTLE; Type 0: Not a Combination uct		Date	Μ	
Packaging # Item Code 1 NDC:50488- 1060-6	60 g Prod	Package Description in 1 BOTTLE; Type 0: Not a Combination uct	02/	Date		
Packaging # Item Code 1 NDC:50488- 1060-6	60 g Prod	Package Description in 1 BOTTLE; Type 0: Not a Combination uct Drmation Application Number or Monograp	02/	Date 01/2020 Marketing Start		Date Marketing End

Labeler - Alexso, Inc (963338061)

Revised: 10/2022

Alexso, Inc