

CAPSAICIN- capsaicin cream
Asclemed USA, Inc.

Capsaicin Cream 0.1%

Drug Facts

Active Ingredient

Capsaicin 0.1%

Purpose

Topical Analgesic

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
- do not use with heating pad or expose area to sunlight

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 treatment area
- do not apply heat to the treated area immediately before or after use

Stop Use and Ask Doctor

Stop Use and Ask Doctor if:

- Condition worsens or does not improve after regular use
- severe burning persists
- redness or blistering occurs

Keep Out of the Reach of Children

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

Uses

Temporarily relieves minor aches and pains of muscles and joints due to:

- simple backache
- arthritis
- strains
- sprains

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

Inactive Ingredients

Aloe barbadensis leaf extract, cetyl alcohol, glyceryl stearate SE, mineral oil, PEG-100 stearate, peppermint oil, phenoxyethanol, propylene glycol, purified water, stearyl alcohol, white petrolatum, xanthan gum

Questions

Questions? Comments?

1-855-361-3993

Other Information

Store at room temperature 15°-30°F (59°-86°F)

Relabeled by:

Enovachem PHARMACEUTICALS

Torrance, CA 90501

Packaging

Relabeled By:



Capsaicin Cream 0.1%

NDC: 76420-753-42

Qty: 42.5



Manufactured For: AVKARE
Source NDC: 50268-198-42
Description: 42.5 g cream in 1 tube
Lot #: 00000000 Exp:
Batch #: 00000000
Drug Status: OTC



(01) 0 0376420 75342 1
(17)
(10) 00000000
(21)

Capsaicin Cream 0.1%
NDC: 76420-753-42
S/N:
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CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION. SEE PACKAGE INSERT.
KEEP OUT OF REACH OF CHILDREN. STORE AT 20-25C (68-77F) [SEE USP CONTROLLED ROOM TEMP].

CAPSAICIN

capsaicin cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76420-753(NDC:50268-198)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)	CAPSAICIN	0.1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CETYL ALCOHOL (UNII: 936JST6JCN)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
XANTHAN GUM (UNII: TTV12P4NEE)	
MINERAL OIL (UNII: T5L8T28FGP)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
WATER (UNII: 059QF0KO0R)	
PETROLATUM (UNII: 4T6H12BN9U)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
GLYCERYL STEARATE/PEG-100 STEARATE (UNII: RD25J5V947)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1	NDC:76420-753-42	1 in 1 CARTON	06/20/2024	
1		42.5 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	12/08/2022	

Labeler - Asclemed USA, Inc. (059888437)

Establishment

Name	Address	ID/FEI	Business Operations
ASCLEMED USA INC. DBA ENOVACHEM		059888437	relabel(76420-753)

Revised: 6/2024

Asclemed USA, Inc.