

MEIJER CAPSAICIN- capsaicin cream
MEIJER, 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.

Active ingredient

Purpose

Capsaicin 0.1%.....Topical analgesic

Uses

For the temporary relief of minor pain associated with:

- Arthritis
- Simple backache
- Muscle strains
- Sprains
- Bruises

Warnings

For external use only

When using this product

- use only as directed
- do not bandage
- do not use with heating pad
- avoid contact with eyes and mucous membranes
- do not apply to wounds, damaged, broken or irritated skin
- a slight burning sensation may occur upon application but generally disappears in several days
- if severe burning occurs, discontinue use
- do not expose the treated area to heat or direct sunlight
- do not use if allergic to capsicum or chili peppers

Stop use and ask a doctor if

- condition worsens
- symptoms persist for more than 7 days or clear up and occur again within a few days
- redness is present
- irritation develops

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.

In case of accidental ingestion, get medical help or contact a Poison Control Center right away.

Directions

Adults and children over 18 years:

- apply generously to affected area not more than 3 to 4 times daily
- massage into painful area until thoroughly absorbed
- wash hands with soap and water after use
- close cap tightly after use

Children 18 years or younger: Ask a doctor

Inactive ingredients

Benzyl alcohol, cetyl alcohol, isopropyl myristate, polyoxyl 40 stearate, purified water, sorbitan, monostearate, sorbitol solution, white petrolatum

DIST. BY MEIJER DISTRIBUTION, INC.

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Made in Korea



MEIJER CAPSAICIN

capsaicin cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41250-256
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 10 g

Inactive Ingredients

Ingredient Name	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
POLYOXYL 40 STEARATE (UNII: 13A4J4NH9I)	
WATER (UNII: 059QF0KO0R)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	
SORBITOL (UNII: 506T60A25R)	
PETROLATUM (UNII: 4T6H12BN9U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41250-256-42	1 in 1 CARTON	10/11/2016	
1		42 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 not final	part348	11/30/2012	

Labeler - MEIJER, INC. (006959555)

Revised: 10/2016

MEIJER, INC.