

LEADER CAPSAICIN - capsaicin cream
CARDINAL HEALTH

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.

Drug Facts

Active ingredient	Purpose
Capsaicin 0.1%.....	Topical analgesic

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, citric acid, glyceryl stearate SE, isopropyl myristate, PEG 100 stearate, petrolatum, purified water, sorbitol

DISTRIBUTED BY CARDINAL HEALTH

DUBLIN, OHIO 43017

CIN 3696283

www.myleader.com

1-800-200-6313

Made in Korea



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LEADER CAPSAICIN

capsaicin cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37205-641
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
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
PEG-100 STEARATE (UNII: YD01N1999R)	
PETROLATUM (UNII: 4T6H12BN9U)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37205-641-13	1 in 1 CARTON		
1		42 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	03/01/2012	

Labeler - CARDINAL HEALTH (097537435)

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