

LEADER CAPSAICIN PAIN RELIEF CREAM- capsaicin cream

Leader

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.

Leader Capsaicin Pain Relief Cream

Drug Facts

Active Ingredient

Capsaicin 0.1%

Purpose

Topical Analgesic

Warnings

For external use only: TEST FIRST ON SMALL AREA OF SKIN.

When using this product:

- Use only as directed
- Do not apply to wounds, damaged, broken or irritated skin
- Do not use if you are allergic to capsicum or chili peppers
- Avoid contact with the eyes or mucous membranes
- 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 bandage
- Do not use with heating pad
- Do not use at the same time as other topical analgesics

Stop Use and Ask Doctor

Stop Use and Ask 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

Keep Out of the Reach of Children

If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Uses

For the temporary relief of minor aches and pains of muscles and joints associated with:

- Arthritis
- Simple Backache

- Strains
- Sprains
- Bruises

If Pregnant or Breast Feeding

Ask a doctor before use

Directions

Adults and Children over 18 years:

- Apply to affected area
- Massage into the painful area until thoroughly absorbed
- Repeat as necessary but not more than 3 to 4 times daily
- WASH HANDS WITH SOAP AND WATER AFTER APPLYING

Children 18 years and younger:

Ask a doctor

Inactive Ingredients

Aloe barbadensis leaf juice, Ethylparaben, Glycerin, Glyceryl monostearate, Mineral Oil, Octadecyl alcohol, Petrolatum, Purified Water, Sodium lauryl Sulfate

Other Information

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

Questions

1 (800) 200- 6313

Distributed by

Cardinal Health

Dublin, Ohio 43017

This product is not manufactured or distributed by Chattem Inc. owner of registered trademark Capzasin HP, 2020 Cardinal Health Leader and Logos are trademarks of Cardinal Health. All other marks are the property of their respective owners

www.myleader.com

Made in China

OUTER BOX



INNER TUBE



LEADER CAPSAICIN PAIN RELIEF CREAM
 capsaicin cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0549
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
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PETROLATUM (UNII: 4T6H12BN9U)	
WATER (UNII: 059QF0K00R)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ETHYL PARABEN (UNII: 14255EXE39)	
MINERAL OIL (UNII: T5L8T28FGP)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0549-1	1 in 1 BOX	05/11/2020	
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 not final	part348	05/11/2020	

Labeler - Leader (097537435)**Registrant** - Trifecta Pharmaceuticals USA LLC (079424163)

Revised: 5/2020

Leader