

LEADER CAPSAICIN PAIN RELIEF CREAM- capsaicin cream
Cardinal Health 110 dba LEADER

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

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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)	
ETHYLPARABEN (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 Drug	M017	05/11/2020	

Labeler - Cardinal Health 110 dba LEADER (063997360)

Registrant - Trifecta Pharmaceuticals USA LLC (079424163)