

SURE RELIEF SR RELIEF - capsaicin cream
International Brand Management, LLC

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

Active Ingredient

Capsaicin 0.025%

Purpose

Purpose

Topical Analgesic

Uses

Uses

for the temporary relief of minor aches and pains of muscles and joints associated with a simple backache,

arthritis, strains and sprains

Warnings

Warnings

For external use only

- This is not a face cream. Do not apply to the face.
- Do not use if allergic to chili peppers or if past allergic reaction to capsaicin
- Do not apply to wounds or damaged, broken, sunburned, chapped or irritated skin.
- Do not bandage tightly
- Do not apply within 1 hour before or after bath, shower, hot tub, sauna or vigorous exercise
- Warm water, perspiration or open pores can intensify the impact of this product and burning sensation.
- Do not use with heating pad, hot water bottle or other source of heat. Doing so can increase risk of serious burns.

When using this product Do not get into eyes and avoid contact with mucous membranes. If contact occurs or if pain, discomfort or skin redness occurs, continuously rinse with cool water and seek medical help.

Discontinue use and consult a doctor if condition worsens or if symptoms persist for more than 7 days or clear

up and occur again within a few days. Stop using and get immediate medical attention if experience burning,

pain, swelling or blistering of the skin. Rare cases of severe burning or blistering have been reported.

If pregnant, breast-feeding or any medical conditions exist, ask a health professional before use.

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

If inhaled, remove the fresh air. If breathing is difficult, get medical attention immediately.

Directions

Directions

- Rotate pump's spout counter-clockwise slightly to unlock; clockwise to lock.
- Before using on children under 18 years of age consult a physician.
- Apply sparingly to affected area not more than 4 times daily. However, for the first use, apply to small area to test for sensitivity or skin reaction.
- Gently massage into skin until fully absorbed.
- Wash hands with soap and water thoroughly after each application to avoid spreading to the eyes or other sensitive mucous membranes.

WARNING: FLAMMABLE PRODUCT

Store in a cool well ventilated area away from heat. Keep away from sparks or open flame.

Inactive Ingredients

Inactive Ingredients:

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aloe Barbadensis Leaf (Aloe Vera Gel) Juice, Aqua (Deionized Water), Arnica Montana Extract, Boswellia Serrata Extract, Cetyl Alcohol, Ethylhexylglycerin, Isopropyl Myristate, PEG-8, Phenoxyethanol, Polysorbate-20, Triethanolamine

FOR QUESTIONS OR COMMENTS:

info@pindintl.com

Drug Facts

Active Ingredient Capsaicin 0.025%	Purpose Topical Analgesic
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Uses
for the temporary relief of minor aches and pains of muscles and joints associated with simple backache, arthritis, strains and sprains

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When using this product: Do not get into eyes and avoid contact with other mucous membranes. If contact occurs or if pain, discomfort or skin redness occurs, continually rinse with cool water and seek medical help.

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Directions

- Rub the pump's spout counter-clockwise slightly to unlock; clockwise to lock.
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- Gently massage into the skin until fully absorbed.
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Inertive Ingredients:

Acrylates/C10-30 Alkyl Acrylate Copolymer, Aloe Barbadensis Leaf (Aloe Vera Gel) Juice, Aqua (Deionized Water), Arnica Montana Extract, Boswellia Serrata Extract, Galy Alcohol, Erythrylglycerin, Isopropyl Myristate, PEG-6, Phenoxyethanol, Polysorbate-20, Triethanolamine.

FOR QUESTIONS OR COMMENTS:
info@guardant.com

Distributed By:
PIMD
8280 NW 27th Ave
Doral, FL 33122



NDC #69837-210-10

Sure Result**SR Relief**

Odorless Pain Relief Cream

Capsaicin 0.025%

Topical use only

4 FL OZ (118 mL)

SURE RELIEF SR RELIEF

capsaicin cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69837-210
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)	CAPSAICIN	.025 mg in .001 g

Inactive Ingredients

Ingredient Name	Strength
(C10-C30)ALKYL METHACRYLATE ESTER (UNII: XH2FQZ38D8)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0K00R)	
ARNICA MONTANA (UNII: O80TY208ZW)	
BOSWELLIA SERRATA RESIN OIL (UNII: 5T1XCE6K8K)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
POLYETHYLENE GLYCOL 800 (UNII: UH6KR4953D)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
TRIETHANOLAMINE GLUTAMATE (UNII: M71CZB7HUY)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69837-210-10	1 in 1 CARTON		
1	NDC:69837-210-09	118 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	03/10/2016	

Labeler - International Brand Management, LLC (079794940)

Establishment

Name	Address	ID/FEI	Business Operations
International Brand Management, LLC		079794940	manufacture(69837-210)

Revised: 3/2016

International Brand Management, LLC