

BIO-SORB- capsaicin cream
Sircle Laboratories, 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.

Bio-Sorb

Drug Facts

Active ingredients

Capsaicin 0.025% w/w (Containing Capsicum Oleoresin 0.0625%)

Purpose

Topical Analgesic

Uses

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

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 other mucous membranes. If contact occurs or if pain, discomfort or skin redness occurs, continually rise 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 cause 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 to fresh air. If breathing is difficult, get medical attention immediately.

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 First use, apply to small area to test for sensitivity or skin reaction.
- Gently massage into the 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.

Inactive ingredients

Aloe Barbadensis Leaf Extract, Bisabolol, Carbomer, Caprylyl Glycol, Cetearyl Alcohol, Cetareth-20, Green Tea (Camellia Sinensis) Leaf Extract, Glycerin, Methylisothiazolinone, PEG-8, Polyglyceryl-3 Oleate, Triethanolamine, Water.

Questions or comments?

Call toll-free 1-888-452-9975; www.sirclelabs.com

PRINCIPAL DISPLAY PANEL - 237 ml Bottle Label

NDC 51021-0302-08

BIO-SORB
Cream

Capsaicin 0.025%

Topical Use Only

SIRCLE
Laboratories

8 fl oz (237ml)

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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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NDC 51021-0302-08

BIO-SORB

Cream

Capsaicin 0.025%

Topical Use Only

Mfg for: Sircle Laboratories, LLC
 Madison, MS 39110

Contact: 1-888-452-9975

www.sirclelabs.com



SIRCLE
 Laboratories

8 fl oz (237ml)

BIO-SORB

capsaicin cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51021-302
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)	CAPSAICIN	0.025 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
LEVOMENOL (UNII: 24WE03BX2T)	
POLYETHYLENE GLYCOL 800 (UNII: UH6KR4953D)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
POLYGLYCERYL-3 OLEATE (UNII: XRQ165498B)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
GLYCERIN (UNII: PDC6A3C0OX)	
TROLAMINE (UNII: 9O3K93S3TK)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51021-302-08	237 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	10/20/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	10/20/2018	

Labeler - Sircle Laboratories, LLC (962175621)

Establishment

Name	Address	ID/FEI	Business Operations
A.I.G. TECHNOLOGIES, INC.		086365223	manufacture(51021-302)

Revised: 7/2021

Sircle Laboratories, LLC