

SIMANIX- simanix pain relieving cream cream

Home Aide Diagnostics, Inc.

Reference Label Set Id: 1a4afc2e-1d77-2243-e054-00144ff88e88

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Silmanix Pain Relieving Cream

PURPOSE: Topical analgesic

ACTIVE INGREDIENTS

Capsaicin 0.0357% -----

----- Counterirritant

Menthol 3% -----

---- Topical analgesic

Histamine DiHydrochloride% -----

-- Topical analgesic

INDICATIONS

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

- Arthritis
- Simple Backache
- Strains
- Sprains
- Bruises

WARNINGS

FOR EXTERNAL USE ONLY.

- Use only as directed
- Do not bandage tightly
- Do not use with a heating pad
- Avoid contact with the eyes or mucous membranes
- Do not apply to wounds, damaged, broken or irritated skin
- A transient burning sensation may occur upon application but generally disappears in several days
- If severe burning sensation occurs, discontinue use immediately and call a doctor
- Do not expose the area treated with product to heat or direct sunlight

STOP USE AND ASK A DOCTOR IF:

- Condition worsens or if symptoms persist for more than 7 days or clear up and occur again within a few days
- Redness is present or irritation develops

DIRECTIONS

- Adults and children over 18 years:
- Apply generously to affected area
- Massage into painful area until thoroughly absorbed into skin
- Repeat as necessary, not more than 3-4 times daily.
- Wash hands with soap and water immediately after use.
- Children 18 years or younger: ask a doctor

Store at 20°-25°C (68°-77 °F). Avoid direct sunlight.

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

If pregnant or breast-feeding, ask a healthcare professional before use

INACTIVE INGREDIENTS

aliphatic alcohol; stearic acid; vaseline; peregol; Carmellose; odium; water

DRUG FACTS
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Simanix

Pain Relieving Cream

Rx. Only

Net Weight: 120 g



Distributed by:
 Home Aide Diagnostics, Inc.
 1072 S. Powerline Road
 Deerfield Beach, FL 33442
 1 (800) 915-0116
 www.homeaide.us



1 69379 01302 5

NDC #: 69379-0013-02
Lot #:
Exp Date:

SIMANIX

simanix pain relieving cream cream

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:69379-013
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)	CAPSAICIN	0.0357 g in 100 g
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	3 g in 100 g
HISTAMINE DIHYDROCHLORIDE (UNII: 3POA0Q644U) (HISTAMINE - UNII:820484N8I3)	HISTAMINE DIHYDROCHLORIDE	0.035 g in 100 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69379-013-02	120 g in 1 BOTTLE; Type 0: Not a Combination Product	07/08/2015	07/08/2015

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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unapproved drug other		07/08/2015	
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Labeler - Home Aide Diagnostics, Inc. (783518983)

Registrant - Zhejiang Bangli Medical Products Cl. Ltd (421295875)

Establishment

Name	Address	ID/FEI	Business Operations
Zhejiang Bangli Medical Products Co. Ltd		421295875	manufacture(69379-013)

Revised: 7/2015

Home Aide Diagnostics, Inc.