# SIMANIX- simanix pain relieving cream cream Home Aide Diagnostics, Inc.

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.

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#### Silmanix Pain Relieiving Cream

**PURPOSE:** Topical analgesic

#### **ACTIVE INGREDIENTS**

Capsaicin 0.0375% ------

----- Counterirritant

Menthol 3% -----

---- Topical analgesic

Histamine DiHydrochloride0.035% ------

----- 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.

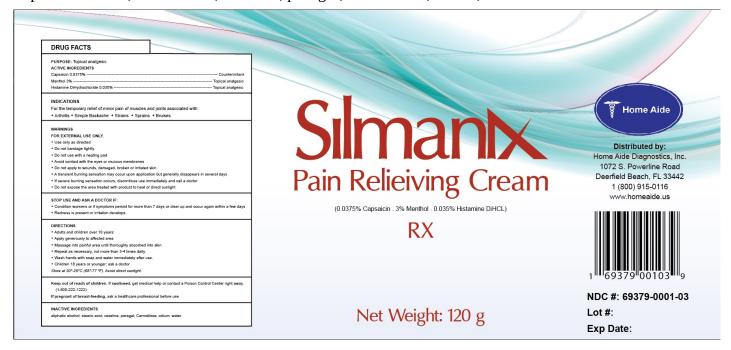
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right

away. (1-800-222-1222)

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

#### **INACTIVE INGREDIENTS**

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



#### **SIMANIX**

simanix pain relieving cream cream

Product Information				
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:69379-001	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)	CAPSAICIN	0.0375 g in 100 g		
MENTHOL (UNII: L7T10 EIP3A) (MENTHOL - UNII:L7T10 EIP3A)	MENTHOL	3 g in 100 g		
HISTAMINE DIHYDRO CHLO RIDE (UNII: 3PO A0 Q644U) (HISTAMINE - UNII: 820484N813)	HISTAMINE DIHYDROCHLORIDE	0.035 g in 100 g		

Packaging				
#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:69379-001-03	120 g in 1 BOTTLE; Type 0: Not a Combination Product	07/08/2015	

Marketing Information				
ı	Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

unapproved drug other	07/08/2015	

## 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(69379-001)	

Revised: 7/2015 Home Aide Diagnostics, Inc.