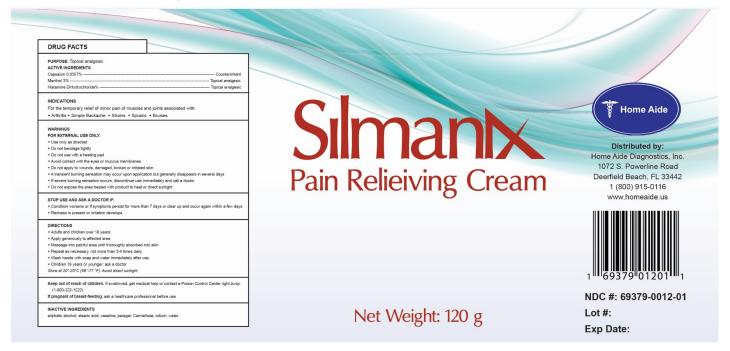
REMATEX- rematex pain relieving cream cream Home Aide Diagnostics, Inc.

Reference Label Set Id: 1a379b78-0658-60dc-e054-00144ff8d46c

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.

Silmanix Pain Relieiving Cream



PURPOSE: Topical analgesic

ACTIVE INGREDIENTS

stamine Dihydrochloride 0.035%
Topical analgesic
enthol 3%
Topical analgesic
apsaicin 0.0375%
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

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.

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

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 Sodium; water;

REMATEX

rematex pain relieving cream cream

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69379-012	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	3 g in 100 g
HISTAMINE DIHYDRO CHLO RIDE (UNII: 3PO A0 Q6 44U) (HISTAMINE - UNII: 820 48 4N8 I3)	HISTAMINE DIHYDROCHLORIDE	0.035 g in 100 g
CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)	CAPSAICIN	0.0375 g in 100 g

Inactive Ingredients	
Ingredient Name	Strength
STEARIC ACID (UNII: 4ELV7Z65AP)	

Dag	1,00	ina
Pac	Kag	IIIg

# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:69379-012- 01	120 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/01/2015	0 7/0 1/20 15

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	07/01/2015	

Labeler - Home Aide Diagnostics, Inc. (783518983)

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

Establishment			
Name	Address	ID/FEI	Business Operations
Zhejiang Bangli Medical Products Co. Ltd		421295875	manufacture(69379-012)

Revised: 7/2015 Home Aide Diagnostics, Inc.