

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 Relieving Cream

DRUG FACTS
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, paregal, Carmellose, odium, water

Silmanix
Pain Relieving Cream

Home Aide

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

1 69379 01201 1

Net Weight: 120 g

NDC #: 69379-0012-01
Lot #:
Exp Date:

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ACTIVE INGREDIENTS

Histamine Dihydrochloride 0.035% -----

----- Topical analgesic

Menthol 3% -----

----- Topical analgesic

Capsaicin 0.0375% -----

----- Topical analgesic

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aliphatic alcohol; stearic acid; vaseline; peregol; 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 DIHYDROCHLORIDE (UNII: 3POA0Q644U) (HISTAMINE - UNII:820484N8I3)		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)			
Packaging			

#	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	07/01/2015

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.