REMATEX- rematex pain relieiving cream cream Home Aide Diganostics, 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.

Rematex Pain Relieving Cream

PURPOSE:

Topical analgesic

ACTIVE INGREDIENTS

Mehyl Salicylate 30% ------

----- Counterirritant

Menthol 6% -----

---- Topical analgesic

Capsaicin 0.035% ------

--- Topical analgesic

INDICATIONS

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

- Arthritis
- Simple Backache
- Strains
- Sprains
- Bruises

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.

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

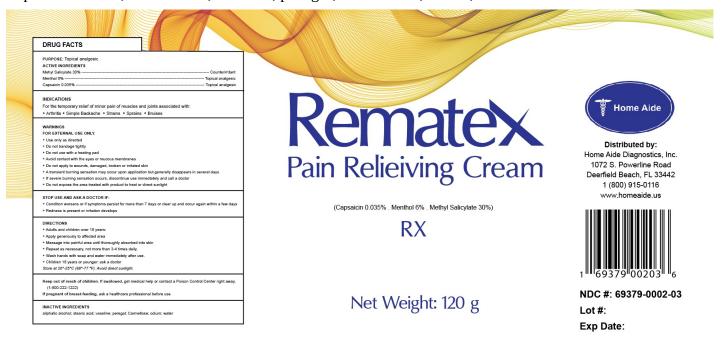
STOP USE AND ASK A DOCTOR IF:

- 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

- 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



REMATEX

rematex pain relieiving cream cream

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:69379-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	6 g in 100 g		
CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)	CAPSAICIN	0.035 g in 100 g		
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	30 g in 100 g		

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:69379-002-03	120 g in 1 BOTTLE; Type 0: Not a Combination Product	07/10/2015	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		07/10/2015	

Labeler - Home Aide Diganostics, Inc. (783518983)

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

Establishment				
Name	Address	ID/FEI	Business Operations	
Zhejiang Bangli Medical Products Cl. Ltd.		421295875	manufacture(69379-002)	

Revised: 7/2015 Home Aide Diganostics, Inc.