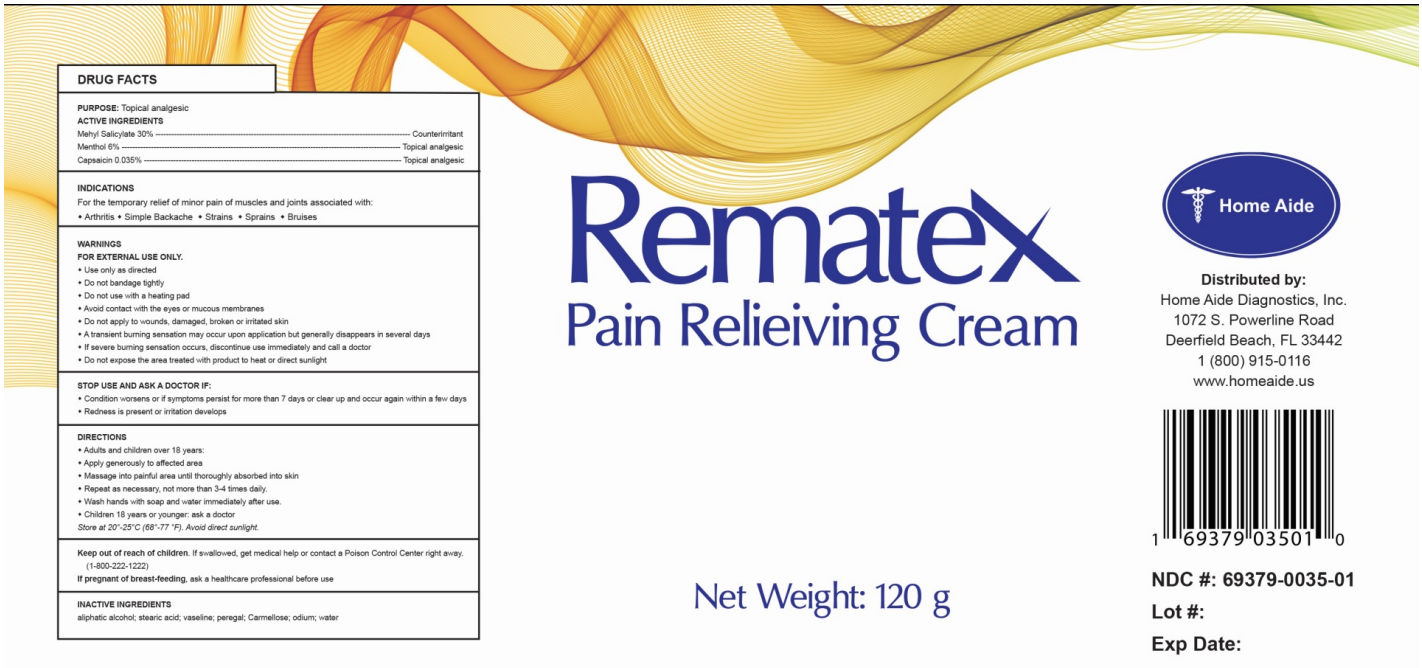
REMATEX- rematex pain relievingcream cream
Home Aide Diagnostics, Inc.
Reference Label Set Id: 1a3849e8-bf43-0bd7-e054-00144ff88e88

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.

Rematex Pain Relieiving 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

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 relievingcream cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69379-035
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
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	30 g in 100 g
CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)	CAPSAICIN	0.035 g in 100 g

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

Packaging				
			Marketing Start	**Marketing End**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69379-035-01	120 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/01/2015	07/10/2015

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(69379-035)

Revised: 7/2015 Home Aide Diagnostics, Inc.