# ROTEX- rotex pain relieving cream cream Home Aide Diagnostics, Inc.

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.

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#### **Rotex Pain Relieving Cream**

**PURPOSE:** Topical analgesic

#### **ACTIVE INGREDIENTS**

Methyl Salicylate 35% ------ Counterirritant Capsaicin 0.038% ------ Counterirritant Menthol 4% ----- 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:

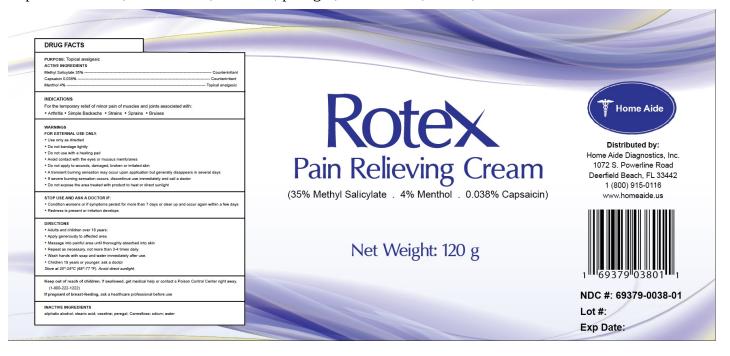
- Condition worsens or if symptoms persist for more than 7 days or clear up and occur again within a few days
- Redness is present or irritation develops

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** 

**TOPICAL** 



#### **ROTEX**

rotex pain relieving cream cream

Route of Administration

Source)	NDC:69379-038
3 (	ource)

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	35 g in 100 g	
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	4 g in 100 g	
CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)	CAPSAICIN	0.038 g in 100 g	

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

ı	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:69379-038- 01	120 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/10/2015	

### **Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	08/10/2015	

## **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(69379-038)	

Revised: 8/2015 Home Aide Diagnostics, Inc.