

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.

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 or breast-feeding, ask a healthcare professional before use

INACTIVE INGREDIENTS

aliphatic alcohol; stearic acid; vaseline; peregal; Carmellose; odium; water

DRUG FACTS

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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 15 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 15 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; peregal; Carmellose; odium; water

Rotex

Pain Relieving Cream

(35% Methyl Salicylate . 4% Menthol . 0.038% Capsaicin)

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

Net Weight: 120 g

1 69379 03801 1

NDC #: 69379-0038-01

Lot #:

Exp Date:

ROTEX

rotex pain relieving cream cream

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:69379-038 |
| Route of Administration | TOPICAL | | |

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) | |

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.