# DUANE READE HOT AND COLD BALM- methyl salicylate and menthol salve Duane Reade

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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#### **Drug Facts**

#### **Active Ingredients Purpose**

Methyl Salicylate 29% ...Topical Analgesic Menthol 7.6% ......Topical Analgesic

#### Uses

temporarily relieves the minor pains associated with:

- arthritis
- cramps
- bruises
- sprains
- backache

### Warnings

#### For external use only

#### Allergy alert:

If prone to allergic reaction from aspirin or salicylates, consult a doctor before use.

#### When using this product

- use only as directed
- avoid contact with eyes or mucous membranes
- do not bandage tightly or with a heating pad
- do not apply to wounds or damaged skin

#### Stop use and ask a doctor if

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

#### If pregnant or breast-feeding,

ask a health professional before use.

#### Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

#### Directions adults and children over 12 years:

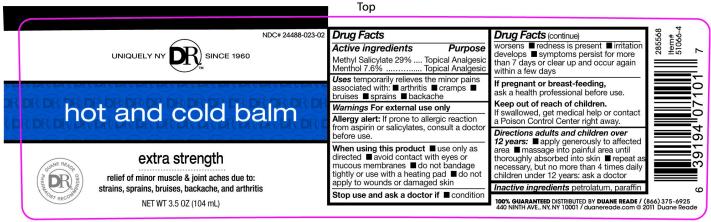
- apply generously to affected area
- massage into painful area until thoroughly absorbed into skin
- repeat as necessary, but no more than 4 times daily

children under 12 years: ask a doctor.

#### **Inactive ingredients**

petrolatum, paraffin

Placeholder text



1.875" x 6.375" (conicalized)

285568\_DR\_hot and cold balm\_3.5oz\_rev9

#### DUANE READE HOT AND COLD BALM

methyl salicylate and menthol salve

| Product Information     |                |                    |               |  |
|-------------------------|----------------|--------------------|---------------|--|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:24488-023 |  |
| Route of Administration | TOPICAL        |                    |               |  |

| Active Ingredient/Active Moiety  |                          |                       |  |  |
|--|--------------------------|-----------------------|--|--|
| Ingredient Name  | <b>Basis of Strength</b> | Strength              |  |  |
| METHYL SALICYLATE (UNII: LAV5U5022Y) (METHYL SALICYLATE - UNII:LAV5U5022Y) | METHYL<br>SALICYLATE     | 30.16 mL<br>in 104 mL |  |  |
| MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)                     | MENTHOL                  | 7.90 mL in 104 mL     |  |  |

| Inactive Ingredients          |          |  |  |
|-------------------------------|----------|--|--|
| Ingredient Name               | Strength |  |  |
| PETROLATUM (UNII: 4T6H12BN9U) |          |  |  |
| PARAFFIN (UNII: 19 O0 E3H2ZE) |          |  |  |
|                               |          |  |  |

| Packaging             |                        |                             |               |                 |      |                    |
|-----------------------|------------------------|-----------------------------|---------------|-----------------|------|--------------------|
| #                     | Item Code              | Package Description         | Marketing     | g Start Date    | Ma   | rketing End Date   |
| 1                     | NDC:24488-023-02       | 104 mL in 1 CANISTER        |               |                 |      |                    |
|                       |                        |                             |               |                 |      |                    |
|                       |                        |                             |               |                 |      |                    |
| Marketing Information |                        |                             |               |                 |      |                    |
|                       | Marketing Category     | Application Number or Monog | raph Citation | Marketing Start | Date | Marketing End Date |
| O                     | TC monograph not final | part348                     |               | 02/28/2011      |      |                    |
|                       |                        |                             |               |                 |      |                    |

## Labeler - Duane Reade (961956229)

### **Registrant** - Creations Garden Natural Products Inc. (961956229)

| Establishment                          |         |           |                     |  |  |
|--|---------|-----------|---------------------|--|--|
| Name                                   | Address | ID/FEI    | Business Operations |  |  |
| Creations Garden Natural Products Inc. |         | 961956229 | manufacture         |  |  |

Revised: 2/2011 Duane Reade