**REXALL VANISHING SCENT PAIN RELIEVING - menthol gel**
**DOLGENCORP, LLC**

*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 ingredient** **Purpose**

Menthol 2.5%.....Topical Analgesic

**Uses** temporarily relieves the minor aches and pains of muscles and joints associated with
- simple backache - atrhritis - strains - bruises - sprains

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

**Uses** temporarily relieves the minor aches and pains of muscles and joints associated with
- simple backache - atrhritis - strains - bruises - sprains

**Warnings**

**For external use only**

**Do not use**

- on wounds or damaged skin
- with a heating pad
- on a child under 12 years of age with arthritis-like conditions

**Ask a doctor before use if** you have redness over the affected area.

**When using this product**
- avoid contact with the eyes or mucous membranes
- do not bandage tightly

**Stop use and ask a doctor if**
- condition worsens or symptoms persist for more than 7 days
- symptoms clear up and occur again within a few days
- excessive skin irritation occurs.

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

**Directions**

**Adults and children 12 years of age and older** - apply to the affected area not more than 3 to 4 times daily.

**Children under 12 years of age** - consult a doctor

**Inactive Ingredients**

purified water, isopropyl alcohol, potassium hydroxide, non0xynol-9, carbomer, camphor, diazolidinyl urea

# REXALL VANISHING SCENT PAIN RELIEVING

menthol gel

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:55910-602 |
| **Route of Administration** | TOPICAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **MENTHOL** (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) | MENTHOL | 27.5 mg in 1 g |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **WATER** (UNII: 059QF0KO0R) | |
| **CARBOMER 934** (UNII: Z135WT9208) | |
| **DIAZOLIDINYL UREA** (UNII: H5RIZ3MPW4) | |
| **ISOPROPYL ALCOHOL** (UNII: ND2M416302) | |
| **CAMPHOR (SYNTHETIC)** (UNII: 5TJD82A1ET) | |
| **NONOXYNOL-9** (UNII: 48Q180SH9T) | |
| **POTASSIUM HYDROXIDE** (UNII: WZH3C48M4T) | |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:55910-602-04 | 1 in 1 CARTON | | |
| **1** | | 57 g in 1 TUBE | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC monograph not final | part348 | 03/14/2011 | |

## Labeler - DOLGENCORP, LLC (068331990)

## Registrant - Pharma Pac, LLC (140807475)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Pharma Pac, LLC | | 140807475 | manufacture |