DOLLAR GENERAL ACNE SPOT MEDICATION - salicylic acid 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.

DRUG FACTS

Active ingredient Purpose

Salicylic Acid 2%......Acne medication

Uses for the treatment of acne

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. Avoid contact with eyes. If contact occurs, flush thoroughly with water.

Uses for the treatment of acne

Warnings

For external use only

Flammable, keep away from open fire or flame

When using this product and other topical acne medications at the same time or immediately following use of this product, increased dryness or irritation of the skin may occur. If this occurs, only one medication should be used unless directed by a doctor.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. Avoid contact with eyes. If contact occurs, flush thoroughly with water.

Directions

- Cleanse skin thoroughly before applying medication
- Cover the affected area entirely up to three times daily
- If excessive dryness or peeling occurs, reduce usage to once a day or every other day
- Recommended for daily use

Inactive Ingredients

Alcohol, Butylene Glycol, Capryloyl Glycine, Cedrus Atlantic Bark Extract, Cinnamomum Zeylanicum Bark Extract, Hexylene Glycol, Hydroxyethylcellulose, Methylparaben, Portulica Oleracea Extract, PPG-2 Isoceth-20 Acetate, Propylene Glycol, Propylparaben,



DOLLAR GENERAL ACNE SPOT MEDICATION

salicylic acid gel

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Product Type HUMAN OTC DRUG Item Code (Source) NDC:55910-601

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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|------------|--|-------------------|---------------|--|--|--|
| | Ingredient Name | Basis of Strength | Strength | | | |
| | SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ) | SALICYLIC ACID | 20 mg in 1 mL | | | |

Inactive Ingredients

| interve ingredients | | | | | | |
|---|----------|--|--|--|--|--|
| Ingredient Name | Strength | | | | | |
| WATER (UNII: 059QF0KO0R) | | | | | | |
| BUTYLENE GLYCOL (UNII: 3XUS85K0RA) | | | | | | |
| MANGANESE GLUCONATE (UNII: 9YY2F980SV) | | | | | | |
| OLIVE OIL (UNII: 6 UYK2W1W1E) | | | | | | |
| CEDRUS ATLANTICA BARK (UNII: ITP1Q41UPF) | | | | | | |
| GLYCERIN (UNII: PDC6 A3C0 OX) | | | | | | |
| HEXYLENE GLYCOL (UNII: KEH0 A3F75J) | | | | | | |
| PURSLANE (UNII: M6S840WXG5) | | | | | | |
| ANHYDRO US TRISO DIUM CITRATE (UNII: RS7A450 LGA) | | | | | | |
| ALCOHOL (UNII: 3K9958V90M) | | | | | | |
| METHYLPARABEN (UNII: A2I8C7HI9T) | | | | | | |
| PROPYLPARABEN (UNII: Z8IX2SC1OH) | | | | | | |

| Packaging | | | | | | |
|-----------|------------------|---------------------|----------------------|--------------------|--|--|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date | | |
| 1 | NDC:55910-601-56 | 1 in 1 CARTON | | | | |
| 1 | | 22 mL in 1 TUBE | | | | |

HYDROXYETHYL CELLULOSE (4000 MPA.S FOR 1% AQUEOUS SOLUTION) (UNII: ZYD53NBL45)

| Marketing Information | | | | | | |
|-------------------------|--|----------------------|--------------------|--|--|--|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | | | |
| OTC monograph not final | part333D | 07/10/2010 | | | | |
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Labeler - DOLGENCORP, LLC (068331990)

Registrant - Pharma Pac, LLC (140807475)

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

Revised: 7/2010 DOLGENCORP, LLC