

CVS ACNE TREATMENT - resorcinol, sulfur cream

CVS Pharmacy

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

Resorcinol 2%.....Acne medication

Sulfur 8%.....Acne Medication

Uses for the treatment and prevention of acne pimples

Keep out of reach of children. In case of accidental ingestion, get medical help or contact a Poison Control Center immediately.

Use for the treatment and prevention of acne pimples

Warnings

For external use only

Do not use - on broken skin - on large areas of the body

When using this product

- apply to affected areas only
 - avoid contact with the eyes, lips and mouth
 - with 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.

Stop use and ask a doctor if excessive skin irritation develops or increases

Keep out of reach of children. In case of accidental ingestion, get medical help or contact a Poison Control Center immediately.

Directions

- Cleanse the skin thoroughly before applying medication
 - Cover the affected area with a thin layer one to three times a day
 - because excessive drying of the skin may occur, start with one application daily, then gradually increase to two to three times daily if needed or as directed by a doctor.
- If bothersome dryness or peeling occurs, reduce application to once a day or every other day.
- use to prevent new pimples from forming

Other information

- keep tightly closed
- keep away from heat

Inactive Ingredients

Water, SD Alcohol 40B, Bentonite, Glyceryl Stearate SE, Propylene Glycol, Titanium Dioxide, Isopropyl Myristate, Fragrance, Iron Oxides, Simethicone, Methylparaben, Propylparaben

Drug Facts

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Resorcinol 2% Acne Medication
Sulfur 8% Acne Medication

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- with 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.

Stop use and ask a doctor if excessive skin irritation develops or increases

Keep out of the reach of children. In case of accidental ingestion, get medical help or contact a Poison Control Center immediately.

Directions

- cleanse the skin thoroughly before applying medication
- cover the entire affected area with a thin layer one to three times a day
- because excessive drying of the skin may occur, start with one application daily, then gradually increase to two to three times daily if needed or as directed by a doctor. If bothersome dryness or peeling occurs, reduce application to once a day or every other day.
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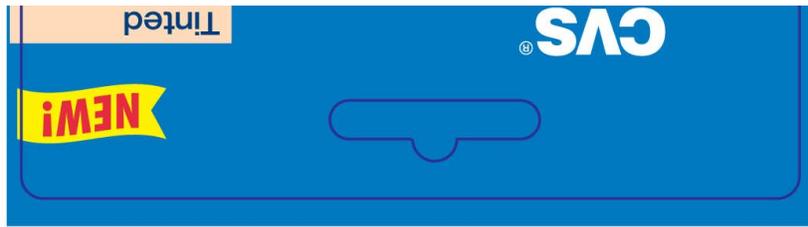
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Compare to the active ingredients in Clearasil®
Stayclear® Adult Acne Control Cream*
Maximum strength
Sulfur resorcinol acne medication
Adult tinted formula
Gently clears up breakouts
Won't overdry skin
NET WT 0.65 OZ (18g)



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Maximum strength
Sulfur resorcinol
acne medication
Adult tinted formula
Gently clears up breakouts
Won't overdry skin



CVS ACNE TREATMENT

resorcinol, sulfur cream

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:59779-813 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|--------------|
| RESORCINOL (UNII: YUL4LO94HK) (RESORCINOL - UNII:YUL4LO94HK) | RESORCINOL | 20 mg in 1 g |
| SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70) | SULFUR | 80 mg in 1 g |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| WATER (UNII: 059QF0KO0R) | |
| BENTONITE (UNII: A3N5ZCN45C) | |
| GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |
| ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS) | |
| DIMETHICONE (UNII: 92RU3N3Y1O) | |
| FERRIC OXIDE RED (UNII: 1K09F3G675) | |
| TALC (UNII: 7SEV7J4R1U) | |
| ALCOHOL (UNII: 3K9958V90M) | |
| METHYLPARABEN (UNII: A2I8C7HI9T) | |
| PROPYLPARABEN (UNII: Z8IX2SC1OH) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:59779-813-68 | 1 in 1 CARTON | | |
| 1 | | 18 g in 1 TUBE | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
|--------------------|--|----------------------|--------------------|

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|-------------------------|----------|------------|--|
| OTC monograph not final | part333D | 07/10/2010 | |
|-------------------------|----------|------------|--|

Labeler - CVS Pharmacy (062312574)

Registrant - Pharma Pac, LLC (140807475)

Establishment

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

Revised: 7/2010

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