

CVS PHARMACY MAXIMUM STRENGTH DANDRUFF- selenium sulfide liquid

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

Selenium Sulfide 1%

Purpose

Anti-dandruff/Anti-seborrheic dermatitis

Uses

for the relief of flaking and itching associated with dandruff and seborrheic dermatitis and to help prevent the chance of recurrence.

Warnings

For external use only.

Ask a doctor before use if you have

seborrheic dermatitis in areas other than the scalp.

When using this product

- avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water.
- for use on color or permed hair, rinse thoroughly.

Stop use and ask a doctor if

condition worsens or does not improve after regular use of this product as directed

Keep out of reach of children.

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

Directions

- Shake well, apply shampoo and rinse thoroughly.
- for best results, use at least twice a week or as directed by a doctor.

Other information

store at room temperature.

Inactive ingredients

Water (Aqua), Sodium Laureth Sulfate, TEA-Lauryl Sulfate, Cocamidopropyl Betaine, Acrylates Copolymer, Citric Acid, Fragrance, Ammonium Chloride, Methylchloroithiazolinone,

Methylisothiazolinone, Menthol, Sodium Hydroxide, Magnesium Aluminum Silicate, Hydroxypropyl Methylcellulose, Blue 1 (CI 42090), Red 33 (CI 17200).

Label Copy



| CVS PHARMACY MAXIMUM STRENGTH DANDRUFF | | | |
|--|----------------|--------------------|---------------|
| selenium sulfide liquid | | | |
| Product Information | | | |
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:59779-719 |
| Route of Administration | TOPICAL | | |
| Active Ingredient/Active Moiety | | | |
| Ingredient Name | | Basis of Strength | Strength |
| SELENIUM SULFIDE (UNII: Z69D9E381Q) (SELENIUM SULFIDE - UNII:Z69D9E381Q) | | SELENIUM SULFIDE | 10 mg in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| WATER (UNII: 059QF0KO0R) | |
| SODIUM LAURETH SULFATE (UNII: BPV390UAP0) | |
| TRIETHANOLAMINE LAURYL SULFATE (UNII: E8458C1KAA) | |
| COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX) | |
| METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:1) (UNII: 74G4R6TH13) | |
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) | |
| AMMONIUM CHLORIDE (UNII: 01Q9PC255D) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |
| METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN) | |
| METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA) | |
| HYPROMELLOSES (UNII: 3NXW29V3WO) | |
| MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC) | |
| MENTHOL (UNII: L7T10EP3A) | |
| FD&C BLUE NO. 1 (UNII: HBR47K3TBD) | |
| D&C RED NO. 33 (UNII: 9DBA0SBB0L) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:59779-719-11 | 325 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 07/18/2017 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part358H | 07/18/2017 | |

Labeler - CVS Pharmacy (062312574)

Registrant - Apollo Health and Beauty Care Inc. (201901209)

Establishment

| Name | Address | ID/FEI | Business Operations |
|------------------------------------|---------|-----------|------------------------|
| Apollo Health and Beauty Care Inc. | | 201901209 | manufacture(59779-719) |

Revised: 7/2017

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