SHOPKO BEAUTY EVERYDAY CLEAN DANDRUFF- pyrithione zinc shampoo Apollo Health and Beauty Care Inc.

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

Pyrithione Zinc 1%

Purpose

Anti-dandruff

Uses

to help prevent recurrence of flaking and itching associated with dandruff.

Warnings

For external use only.

When using this product

avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water.

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

- for best results, use at least twice a week or as directed by a doctor.
- wet hair, massage onto scalp and rinse.
- repeat if desired.

Inactive ingredients

Water (Aqua), Sodium Laureth Sulfate, Sodium Chloride, Acrylates Copolymer, Glycol Distearate, Cocamidopropyl Betaine, Cocamide MEA, Laureth-4, Fragrance (Parfum), Sodium Hydroxide, Tetrasodium EDTA, Methylchloroisothiazolinone, Methylisothiazolinone, Blue 1 (CI 42090), Red 33 (CI 17200).

Questions or comments?

1-866-695-3030

Label Copy





EVERYDAY CLEAN

DANDRUFF SHAMPOO

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"This product is not manufactured or distributed by Proctor & Gamble, distributor of Head & Shoulders".

Made in Canada.

Manufactured by: Apollo Health & Beauty Care Inc. 1 Apollo Place, Toronto, ON M3J 0H2

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By Refund or Exchange



06-2250

SHOPKO BEAUTY EVERYDAY CLEAN DANDRUFF

pyrithione zinc shampoo

Product Information

Product Type HUMAN OTC DRUG

Item Code (Source)

NDC:63148-001

Route of Administration

TOPICAL

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|---------------|
| PYRITHIONE ZINC (UNII: R953O2RHZ5) (PYRITHIONE ZINC - UNII:R953O2RHZ5) | PYRITHIONE ZINC | 10 mg in 1 mL |

| Inactive Ingredients | |
|---|----------|
| Ingredient Name | Strength |
| WATER (UNII: 059QF0KO0R) | |
| SO DIUM LAURETH SULFATE (UNII: BPV390 UAP0) | |
| METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:1) (UNII: 74G4R6TH13) | |
| GLYCOL DISTEARATE (UNII: 13W7MDN21W) | |
| COCAMIDO PRO PYL BETAINE (UNII: 50 CF3 O 11 KX) | |
| COCO MONOETHANOLAMIDE (UNII: C80684146D) | |
| LAURETH-4 (UNII: 6HQ855798J) | |
| SO DIUM HYDRO XIDE (UNII: 55X04QC32I) | |
| EDETATE SO DIUM (UNII: MP1J8420LU) | |
| METHYLCHLORO ISO THIAZO LINO NE (UNII: DEL7T5QRPN) | |
| METHYLISOTHIAZOLINONE (UNII: 229 D0 E1QFA) | |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD) | |
| D&C RED NO.33 (UNII: 9DBA0SBB0L) | |

| Packaging | | | | |
|-----------------|--|-------------------------|-----------------------|--|
| # Item Code | Package Description | Marketing Start Date | Marketing End Date | |
| 1 NDC:63148-001 | 701 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 02/15/2018 | | |

| Marketing Information | | | | |
|-----------------------|--|----------------------|--------------------|--|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| OTC monograph final | part358H | 02/15/2018 | | |
| | | | | |

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

${f Registrant}$ - Apollo Health and Beauty Care Inc. (201901209)

| Establishment | | | | | |
|------------------------------------|---------|-----------|----------------------------|--|--|
| Name | Address | ID/FEI | Business Operations | | |
| Apollo Health and Beauty Care Inc. | | 201901209 | manufacture(63148-001) | | |

Revised: 2/2018 Apollo Health and Beauty Care Inc.