**NIOXIN SCALP RECOVERY SOOTHING SERUM- pyrithione zinc lotion/shampoo**
**The Wella Corporation**

*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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**Nioxin Scalp Recovery Soothing Serum**

***Drug Facts***

**Active ingredient**

Pyrithione Zinc 0.1%

**Purpose**

Anti-dandruff, Anti-seborrheic dermatitis

**Uses**

- helps prevent recurrence of flaking, itching, irritation, scaling and redness associated with dandruff and seborrheic dermatitis.

**Warnings**

**For external use only.**

**Ask a doctor before use if you have a condition that covers a large area of the body.**

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

**Directions**

- apply to affected areas one to four times daily or as directed by a doctor.

**Inactive ingredients**

water, stearamidopropyl dimethylamine, cetyl alcohol, hydroxyethylcellulose, quaternium-18, benzyl alcohol, phenoxyethanol, stearyl alcohol, PEG-2M, dimethicone,

cetearyl alcohol, methylparaben, propylparaben, fragrance, glyceryl stearate, oleyl alcohol, citric acid, polysorbate 60, mentha piperita (peppermint) oil, menthol, mentha arvensis leaf oil, yeast extract, camellia sinensis leaf extract, lecithin, PPG-26-buteth-26, saccharomyces/magnesium ferment, dimethyl isosorbide, carnitine HCL, PEG/PPG-18/18 dimethicone, ethoxydiglycol, oryza sativa (rice) bran, PEG-40 hydrogenated castor oil, biotin/folic acid/cyanocobalamin/niacinamide/pantothenic acid/pyridoxine/riboflavin/thiamine/yeast polypeptides, saccharomyces/iron ferment, saccharomyces/copper ferment, saccharomyces/silicon ferment, saccharomyces/zinc ferment, acacia senegal gum, ubiquinone.

**Questions?**

**1-800-935-5273**

Dist. by
THE WELLA CORPORATION,
WOODLAND HILLS, CA 91367

**PRINCIPAL DISPLAY PANEL - 100 mL Bottle Carton**

**NIOXIN ®**
**SCALP RECOVERY ®**

*For a dry, itchy scalp*

**PYRITHIONE ZINC**
**DANDRUFF AND**
**SEBORRHEIC**
**DERMATITIS**
**TREATMENT**

SOOTHING
SERUM

**100% FLAKE FREE**
ELIMINATION OF
VISIBLE FLAKES WITH
REGULAR USE*

100 mL (3.38 FL OZ)


**NIOXIN SCALP RECOVERY SOOTHING SERUM**

pyrithione zinc lotion/shampoo

## Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:69282-006 |
| **Route of Administration** | TOPICAL | | |

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **PYRITHIONE ZINC** (UNII: R953O2RHZ5) (PYRITHIONE ZINC - UNII:R953O2RHZ5) | PYRITHIONE ZINC | 0.1 g in 100 mL |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **WATER** (UNII: 059QF0KO0R) | |
| **STEARAMIDOPROPYL DIMETHYLAMINE** (UNII: K7VEI00UFR) | |
| **CETYL ALCOHOL** (UNII: 936JST6JCN) | |
| **QUATERNIUM-18** (UNII: O7757NO1VL) | |
| **BENZYL ALCOHOL** (UNII: LKG8494WBH) | |
| **PHENOXYETHANOL** (UNII: HIE492ZZ3T) | |
| **STEARYL ALCOHOL** (UNII: 2KR89I4H1Y) | |
| **POLYETHYLENE OXIDE 100000** (UNII: V46Y6OJ5QB) | |
| **DIMETHICONE** (UNII: 92RU3N3Y1O) | |
| **CETOSTEARYL ALCOHOL** (UNII: 2DMT128M1S) | |
| **METHYLPARABEN** (UNII: A2I8C7HI9T) | |
| **PROPYLPARABEN** (UNII: Z8IX2SC1OH) | |
| **GLYCERYL MONOSTEARATE** (UNII: 230OU9XXE4) | |
| **OLEYL ALCOHOL** (UNII: 172F2WN8DV) | |
| **CITRIC ACID MONOHYDRATE** (UNII: 2968PHW8QP) | |
| **POLYSORBATE 60** (UNII: CAL22UVI4M) | |
| **PEPPERMINT OIL** (UNII: AV092KU4JH) | |
| **MENTHOL, UNSPECIFIED FORM** (UNII: L7T10EIP3A) | |
| **MENTHA ARVENSIS LEAF OIL** (UNII: 1AEY1M553N) | |
| **YEAST, UNSPECIFIED** (UNII: 3NY3SM6B8U) | |
| **GREEN TEA LEAF** (UNII: W2ZU1RY8B0) | |
| **PPG-26-BUTETH-26** (UNII: 2II1K6TZ4P) | |
| **DIMETHYL ISOSORBIDE** (UNII: SA6A6V432S) | |
| **LEVOCARNITINE HYDROCHLORIDE** (UNII: J3Y5E6IKS3) | |
| **PEG/PPG-18/18 DIMETHICONE** (UNII: 9H0AO7T794) | |
| **DIETHYLENE GLYCOL MONOETHYL ETHER** (UNII: A1A1I8X02B) | |
| **RICE BRAN** (UNII: R60QEP13IC) | |
| **POLYOXYL 40 HYDROGENATED CASTOR OIL** (UNII: 7YC686GQ8F) | |
| **ACACIA** (UNII: 5C5403N26O) | |
| **UBIDECARENONE** (UNII: EJ27X76M46) | |

## Packaging

| | | | Marketing Start | Marketing End |
|---|---|---|---|---|

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:69282-006-50 | 1 in 1 CARTON | 07/01/2016 | |
| **1** | | 50 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | | |
| **2** | NDC:69282-006-10 | 1 in 1 CARTON | 07/01/2016 | |
| **2** | | 100 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC monograph final | part358H | 07/01/2016 | |

## Labeler - The Wella Corporation (001399815)

## Registrant - Coty US LLC (039056361)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Thibiant International, Inc. | | 118542196 | manufacture(69282-006) |

Revised: 12/2022 The Wella Corporation