

## **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.*

-----

### **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<sup>®</sup>**  
**SCALP RECOVERY<sup>®</sup>**

*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)



**Drug Facts**

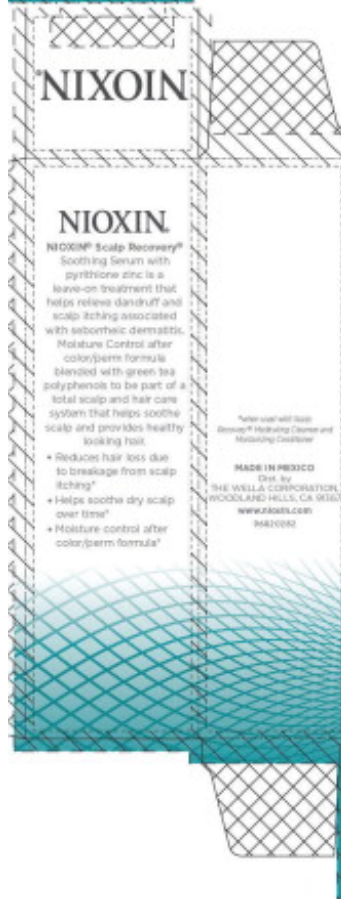
**Active ingredient:** Pyruvate (1.0%), Zinc Pyrithione (1.0%), Salicylic Acid (1.0%), Menthol (0.1%), Camphor (0.1%), Eucalyptus Oil (0.1%), Tea Tree Oil (0.1%), Aloe Vera (0.1%), Glycerin (0.1%), Hydroxyethylcellulose (0.1%), Carbomer (0.1%), Sodium Hydroxide (0.1%), Water (Aq. 99.9%).

**Other ingredients:** Pyruvate, Zinc Pyrithione, Salicylic Acid, Menthol, Camphor, Eucalyptus Oil, Tea Tree Oil, Aloe Vera, Glycerin, Hydroxyethylcellulose, Carbomer, Sodium Hydroxide, Water.

**Warnings:** For external use only. Do not use on broken skin or on areas that are red, raw, or itchy. Avoid contact with eyes. Do not use if you have a known allergy to any of the ingredients. Do not use if you are pregnant or breastfeeding.

**Directions:** Apply to the scalp and hair. Massage gently. Use daily. For best results, use with Nioxin Shampoo. For dry scalp, use with Nioxin Moisture Control. For color/permed hair, use with Nioxin Moisture Control after coloring.

**Net Content:** 100 mL (3.38 FL. OZ.)



**NIOXIN**

**NIOXIN<sup>®</sup> Scalp Recovery<sup>®</sup>**  
Soothing Serum with pyrithione zinc is a leave-on treatment that helps relieve dandruff and scalp itching associated with seborrheic dermatitis. Moisture Control after color/permed formula is blended with green tea polyphenols to be part of a total scalp and hair care system that helps soothe scalp and provides healthy looking hair.

- Reduces hair loss due to breakage from scalp itching\*
- Helps soothe dry scalp over time\*
- Moisture control after color/permed formula\*

\*After use with Nioxin Shampoo<sup>®</sup> Hydrating Conditioner and Moisturizing Conditioner

**MADE IN MEXICO**  
Dist. by THE WELLA CORPORATION, WOODLAND HILLS, CA 91367  
[WWW.NIOXIN.COM](http://WWW.NIOXIN.COM)  
NAX1000

**NIOXIN SCALP RECOVERY SOOTHING SERUM**  
pyrithione zinc lotion/shampoo

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69282-006
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>PYRITHIONE ZINC</b> (UNII: R953O2RHZ5) (PYRITHIONE ZINC - UNII:R953O2RHZ5)	PYRITHIONE ZINC	0.1 g in 100 mL

**Inactive Ingredients**

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