

## **NIOXIN SCALP RECOVERY ANTI-DANDRUFF SYSTEM- pyrithione zinc** **Wella Operations US LLC**

*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 Anti-Dandruff Kit**

#### **Drug Facts**

##### **Active ingredient**

Pyrithione zinc 1% (Medicating Cleanser)

Pyrithione zinc 0.5% (Moisturizing Conditioner)

Pyrithione zinc 0.1% (Soothing Serum)

##### **Purpose**

Anti-dandruff

##### **Uses**

- helps 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.** If swallowed, get medical help or contact a Poison Control Center right away.

##### **Directions**

###### **MEDICATING CLEANSER**

- For best results, use at least twice a week or as directed by a doctor
- Use daily for maximum dandruff control
- Massage on to wet scalp and hair. Rinse. Repeat if desired.

###### **MOISTURIZING CONDITIONER**

- For best results, use at least twice a week or as directed by a doctor
- Use daily for maximum dandruff control
- Apply to wet scalp and hair. Leave for 1-3 minutes. Rinse well.

###### **SOOTHING SERUM**

- Apply after usage of Medicating Cleanser and Moisturizing Conditioner to scalp.
- Apply to affected areas one to four times daily or as directed by a doctor.

## MEDICATING CLEANSER

**Inactive ingredients** water, sodium laureth sulfate, PEG-3 distearate, sodium laureth-8 sulfate, sodium chloride, cocamidopropyl betaine, acrylates/stearate-20 methacrylate copolymer, magnesium laureth-8 sulfate, magnesium laureth sulfate, sodium oleth sulfate, fragrance, sodium benzoate, citric acid, DMDM hydantoin, mentha arvensis leaf oil, mentha piperita (peppermint) oil, magnesium oleth sulfate, sodium hydroxide, polyquaternium-10, propylene glycol, benzoic acid, linalool, hexyl cinnamal, camellia sinensis leaf extract, sodium polynaphthalenesulfonate, benzyl alcohol, limonene, geraniol, cellulose gum, yeast extract, niacinamide, tocopheryl acetate, panthenol, biotin, lecithin, ethoxydiglycol, maltodextrin, methylparaben, glucose, propylparaben, lactic acid, achillea millefolium extract, betula alba leaf extract, urtica dioica (nettle) extract, salvia officinalis (sage) leaf extract, rosmarinus officinalis (rosemary) leaf extract, equisetum arvense extract, potassium sorbate, calcium pantothenate, inositol, tartaric acid, caramel.

## MOISTURIZING CONDITIONER

**Inactive ingredients** water, stearyl alcohol, cetyl alcohol, stearamidopropyl dimethylamine, dimethicone, glutamic acid, benzyl alcohol, phenoxyethanol, fragrance, methylparaben, mentha arvensis leaf oil, mentha piperita (peppermint) oil, citric acid, propylene glycol, linalool, hexyl cinnamal, camellia sinensis leaf extract, limonene, sodium polynaphthalenesulfonate, geraniol, DMDM hydantoin, cellulose gum, yeast extract, niacinamide, panthenol, biotin, lecithin, tocopheryl acetate, ethoxydiglycol, maltodextrin, glucose, propylparaben, lactic acid, sodium benzoate, equisetum arvense extract, rosmarinus officinalis (rosemary) leaf extract, salvia officinalis (sage) leaf extract, urtica dioica (nettle) extract, achillea millefolium extract, betula alba leaf extract, potassium sorbate, inositol, calcium pantothenate, tartaric acid, caramel.

## SOOTHING SERUM

**Inactive ingredients** water, cetyl alcohol, stearamidopropyl dimethylamine, stearyl alcohol, distearyldimonium chloride, hydroxyethylcellulose, benzyl alcohol, phenoxyethanol, PEG-2M, dimethicone, fragrance, cetearyl alcohol, methylparaben, glyceryl stearate, oleyl alcohol, mentha arvensis leaf oil, mentha piperita (peppermint) oil, citric acid, polysorbate 60, propylene glycol, camellia sinensis leaf extract, linalool, hexyl cinnamal, limonene, silica, geraniol, benzyl salicylate, alpha-isomethyl ionone, sodium polynaphthalenesulfonate, yeast extract, disodium phosphate, niacinamide, panthenol, biotin, lecithin, tocopheryl acetate, ethoxydiglycol, DMDM hydantoin, maltodextrin, cellulose gum, sodium phosphate, BHT, glucose, propylparaben, lactic acid, sodium benzoate, betula alba leaf extract, achillea millefolium extract, urtica dioica (nettle) extract, salvia officinalis (sage) leaf extract, rosmarinus officinalis (rosemary) leaf extract, equisetum arvense extract, potassium sorbate, calcium pantothenate, inositol, caramel, tartaric acid

## **Questions?**

**1-800-935-5273**

**MADE IN U.S.A. of U.S. and/or imported ingredients**

Dist. Wella Operations US LLC,

Calabasas, CA 91302

www.nioxin.com

1-800-935-5273

**NIOXIN®**

**SCALP RECOVERY**

**ANTI-DANDRUFF SYSTEM FOR ITCHY, FLAKY SCALP**

COMBATS DANDRUFF FROM THE 1ST USE

**STEP 1**

PYRITHIONE ZINC  
MEDICATING CLEANSER

**200 mL ( 6.76 FL OZ )**

**STEP 2**

PYRITHIONE ZINC  
MOISTURIZING CONDITIONER

**200 mL ( 6.76 FL OZ )**

**STEP 3**

PYRITHIONE ZINC  
SOOTHING SERUM

**100 mL ( 3.38 FL OZ )**

**NIOXIN®**  
**SCALP RECOVERY®**  
ANTI-DANDRUFF SYSTEM  
FOR ITCHY, FLAKY SCALP

The **#1\*** salon brand for  
**THICKER, FULLER** hair\*\*



SUPPORTED BY  
The **Institute of**  
**Trichologists**



**SCALP RECOVERY®**  
ANTI-DANDRUFF SYSTEM  
FOR ITCHY, FLAKY SCALP



## NIOXIN SCALP RECOVERY ANTI-DANDRUFF SYSTEM

pyrithione zinc kit

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:82157-006
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### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82157-006-99	1 in 1 CARTON; Type 1: Convenience Kit of Co-Package	12/01/2022	

### Quantity of Parts

Part #	Package Quantity	Total Product Quantity
<b>Part 1</b>	1 BOTTLE, PLASTIC	200 mL
<b>Part 2</b>	1 BOTTLE, PLASTIC	200 mL
<b>Part 3</b>	1 BOTTLE, PLASTIC	100 mL

### Part 1 of 3

## NIOXIN SCALP RECOVERY MEDICATING CLEANSER

pyrithione zinc shampoo

### Product Information

<b>Item Code (Source)</b>	NDC:82157-003
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Route of Administration TOPICAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>PYRITHIONE ZINC</b> (UNII: R953O2RHZ5) (PYRITHIONE ZINC - UNII:R953O2RHZ5)	PYRITHIONE ZINC	1 g in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)	
<b>COCAMIDOPROPYL BETAINE</b> (UNII: 5OCF3O11KX)	
<b>MAGNESIUM LAURETH SULFATE</b> (UNII: UKW9G007TZ)	
<b>ALPHA-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>INOSITOL</b> (UNII: 4L6452S749)	
<b>LACTIC ACID</b> (UNII: 33X04XA5AT)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>MENTHA ARVENSIS LEAF OIL</b> (UNII: 1AEY1M553N)	
<b>BENZYL ALCOHOL</b> (UNII: LKG8494WBH)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>LIMONENE, (+/-)-</b> (UNII: 9MC3I34447)	
<b>DEXTROSE, UNSPECIFIED FORM</b> (UNII: IY9XDZ35W2)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>FORMALDEHYDE/SODIUM NAPHTHALENESULFONATE COPOLYMER (3000 MW)</b> (UNII: 90D834OZUI)	
<b>YEAST, UNSPECIFIED</b> (UNII: 3NY3SM6B8U)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>SODIUM LAURETH-8 SULFATE</b> (UNII: YP8U3694P0)	
<b>SAGE</b> (UNII: 065C5D077J)	
<b>CALCIUM PANTOTHENATE</b> (UNII: 568ET80C3D)	
<b>MALTODEXTRIN</b> (UNII: 7CVR7L4A2D)	
<b>EQUISETUM ARVENSE BRANCH</b> (UNII: 1L0VKZ185E)	
<b>CARAMEL</b> (UNII: T9D99G2B1R)	
<b>NIACINAMIDE</b> (UNII: 25X51I8RD4)	
<b>ACHILLEA MILLEFOLIUM</b> (UNII: 2FXJ6SW4PK)	
<b>SODIUM OLEYL SULFATE</b> (UNII: 46F21X4586)	
<b>MAGNESIUM OLETH SULFATE</b> (UNII: LCQ4WP3DTL)	
<b>DMDM HYDANTOIN</b> (UNII: BYR0546TOW)	
<b>PEPPERMINT OIL</b> (UNII: AV092KU4JH)	
<b>GREEN TEA LEAF</b> (UNII: W2ZU1RY8B0)	
<b>GERANIOL</b> (UNII: L837108USY)	
<b>BIOTIN</b> (UNII: 6S06U10H04)	
<b>DIETHYLENE GLYCOL MONOETHYL ETHER</b> (UNII: A1A1I8X02B)	
<b>.ALPHA.-HEXYLCINNAMALDEHYDE</b> (UNII: 7X6O37OK2I)	
<b>BETULA PUBESCENS LEAF</b> (UNII: 845OH00300)	
<b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)	
<b>BENZOIC ACID</b> (UNII: 8SKN0B0MIM)	
<b>CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM</b> (UNII: K679OBS311)	
<b>TARTARIC ACID</b> (UNII: W4888I119H)	

<b>PANTHENOL</b> (UNII: WW9CM0067Z)
<b>SODIUM LAURETH-3 SULFATE</b> (UNII: BPV390UAP0)
<b>LINALOOL, (+/-)-</b> (UNII: D81QY6I88E)
<b>WATER</b> (UNII: 059QF0KO0R)
<b>PEG-3 DISTEARATE</b> (UNII: 8420ECX438)
<b>POLYQUATERNIUM-10 (400 MPAS AT 2%)</b> (UNII: HB1401PQFS)
<b>URTICA DIOICA LEAF</b> (UNII: X6M0DRN46Q)
<b>ROSEMARY</b> (UNII: IJ67X351P9)
<b>ETHYL ACRYLATE/METHACRYLIC ACID/STEARETH-20 METHACRYLATE COPOLYMER</b> (UNII: EPA1872R1N)
<b>MAGNESIUM LAURETH-8 SULFATE</b> (UNII: 2OTJ9LF5UA)
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82157-003-20	200 mL in 1 BOTTLE, PLASTIC; Type 1: Convenience Kit of Co-Package		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M032	12/01/2022	

### Part 2 of 3

## NIOXIN SCALP RECOVERY MOISTURIZING CONDITIONER

pyrithione zinc lotion

### Product Information

<b>Item Code (Source)</b>	NDC:82157-004
<b>Route of Administration</b>	TOPICAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>PYRITHIONE ZINC</b> (UNII: R953O2RHZ5) (PYRITHIONE ZINC - UNII:R953O2RHZ5)	PYRITHIONE ZINC	0.5 g in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)	

<b>SAGE</b> (UNII: 065C5D077J)
<b>CALCIUM PANTOTHENATE</b> (UNII: 568ET80C3D)
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)
<b>ROSEMARY</b> (UNII: IJ67X351P9)
<b>GREEN TEA LEAF</b> (UNII: W2ZU1RY8B0)
<b>DIETHYLENE GLYCOL MONOETHYL ETHER</b> (UNII: A1A1I8X02B)
<b>INOSITOL</b> (UNII: 4L6452S749)
<b>TARTARIC ACID</b> (UNII: W4888I119H)
<b>LIMONENE, (+/-)-</b> (UNII: 9MC3I34447)
<b>EQUISETUM ARVENSE BRANCH</b> (UNII: 1L0VKZ185E)
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)
<b>MALTODEXTRIN</b> (UNII: 7CVR7L4A2D)
<b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)
<b>ACHILLEA MILLEFOLIUM</b> (UNII: 2FXJ6SW4PK)
<b>.ALPHA.-HEXYLCINNAMALDEHYDE</b> (UNII: 7X6O37OK2I)
<b>GERANIOL</b> (UNII: L837108USY)
<b>FORMALDEHYDE/SODIUM NAPHTHALENESULFONATE COPOLYMER (3000 MW)</b> (UNII: 90D834OZUI)
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)
<b>PEPPERMINT OIL</b> (UNII: AV092KU4JH)
<b>NIACINAMIDE</b> (UNII: 25X51I8RD4)
<b>DMDM HYDANTOIN</b> (UNII: BYR0546TOW)
<b>LACTIC ACID</b> (UNII: 33X04XA5AT)
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)
<b>CARAMEL</b> (UNII: T9D99G2B1R)
<b>LINALOOL, (+/-)-</b> (UNII: D81QY6I88E)
<b>URTICA DIOICA LEAF</b> (UNII: X6M0DRN46Q)
<b>ALPHA-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)
<b>PANTHENOL</b> (UNII: WW9CM0O67Z)
<b>BIOTIN</b> (UNII: 6SO6U10H04)
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)
<b>WATER</b> (UNII: 059QF0KO0R)
<b>MENTHA ARVENSIS LEAF OIL</b> (UNII: 1AEY1M553N)
<b>YEAST, UNSPECIFIED</b> (UNII: 3NY3SM6B8U)
<b>BETULA PUBESCENS LEAF</b> (UNII: 84SOH0O3OO)
<b>CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM</b> (UNII: K679OBS311)
<b>DEXTROSE, UNSPECIFIED FORM</b> (UNII: IY9XDZ35W2)
<b>STEARYL ALCOHOL</b> (UNII: 2KR89I4H1Y)
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)
<b>STEARAMIDOPROPYL DIMETHYLAMINE</b> (UNII: K7VEI00UFR)
<b>GLUTAMIC ACID</b> (UNII: 3KX376GY7L)
<b>BENZYL ALCOHOL</b> (UNII: LKG8494WBH)

<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82157-004-20	200 mL in 1 BOTTLE, PLASTIC; Type 1: Convenience Kit of Co-Package		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M032	12/01/2022	

## Part 3 of 3

### NIOXIN SCALP RECOVERY SOOTHING SERUM

pyrithione zinc lotion

## Product Information

Item Code (Source)	NDC:82157-005
Route of Administration	TOPICAL

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

Ingredient Name	Strength
<b>URTICA DIOICA LEAF</b> (UNII: X6M0DRN46Q)	
<b>EQUISETUM ARVENSE BRANCH</b> (UNII: 1L0VKZ185E)	
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
<b>YEAST, UNSPECIFIED</b> (UNII: 3NY3SM6B8U)	
<b>ROSEMARY</b> (UNII: IJ67X351P9)	
<b>BUTYLATED HYDROXYTOLUENE</b> (UNII: 1P9D0Z171K)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>LIMONENE, (+/-)-</b> (UNII: 9MC3I34447)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>PANTHENOL</b> (UNII: WW9CM0O67Z)	
<b>NIACINAMIDE</b> (UNII: 25X5118RD4)	
<b>LINALOOL, (+/-)-</b> (UNII: D81QY6I88E)	
<b>CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM</b> (UNII: K679OBS311)	
<b>FORMALDEHYDE/SODIUM NAPHTHALENESULFONATE COPOLYMER (3000 MW)</b> (UNII: 90D834OZUI)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>CARAMEL</b> (UNII: T9D99G2B1R)	
<b>ISOMETHYL-.ALPHA.-IONONE</b> (UNII: 9XP4LC555B)	
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	



<b>PEPPERMINT OIL</b> (UNII: AV092KU4JH)
<b>ALPHA-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)
<b>BENZYL ALCOHOL</b> (UNII: LKG8494WBH)
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)
<b>STEARYL ALCOHOL</b> (UNII: 2KR89I4H1Y)
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)
<b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)
<b>BIOTIN</b> (UNII: 6SO6U10H04)
<b>ANHYDROUS DEXTROSE</b> (UNII: 5SLOG7R0OK)
<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)
<b>ACHILLEA MILLEFOLIUM</b> (UNII: 2FXJ6SW4PK)
<b>HYDROXYETHYL CELLULOSE, UNSPECIFIED</b> (UNII: T4V6TWG28D)
<b>STEARAMIDOPROPYL DIMETHYLAMINE</b> (UNII: K7VEI00UFR)
<b>POLYSORBATE 60</b> (UNII: CAL22UVI4M)
<b>POLYETHYLENE OXIDE 100000</b> (UNII: V46Y6OJ5QB)
<b>OLEYL ALCOHOL</b> (UNII: 172F2VN8DV)
<b>MENTHA ARVENSIS LEAF OIL</b> (UNII: 1AEY1M553N)
<b>SODIUM PHOSPHATE, DIBASIC, ANHYDROUS</b> (UNII: 22ADO53M6F)
<b>DMDM HYDANTOIN</b> (UNII: BYR0546TOW)
<b>MALTODEXTRIN</b> (UNII: 7CVR7L4A2D)
<b>TARTARIC ACID</b> (UNII: W4888I119H)
<b>SAGE</b> (UNII: 065C5D077J)
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)
<b>INOSITOL</b> (UNII: 4L6452S749)
<b>BENZYL SALICYLATE</b> (UNII: WAO5MKN9TU)
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)
<b>GREEN TEA LEAF</b> (UNII: W2ZU1RY8B0)
<b>SODIUM PHOSPHATE</b> (UNII: SE337SVY37)
<b>DISTEARYLDIMONIUM CHLORIDE</b> (UNII: OM9573ZX3X)
<b>.ALPHA.-HEXYLCINNAMALDEHYDE</b> (UNII: 7X6O37OK2I)
<b>GERANIOL</b> (UNII: L837108USY)
<b>BETULA PUBESCENS LEAF</b> (UNII: 84SOH00300)
<b>LACTIC ACID</b> (UNII: 33X04XA5AT)
<b>CALCIUM PANTOTHENATE</b> (UNII: 568ET80C3D)

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82157-005-10	100 mL in 1 BOTTLE, PLASTIC; Type 1: Convenience Kit of Co-Package		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M032	12/01/2022	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M032	12/01/2022	

**Labeler** - Wella Operations US LLC (117781338)

Revised: 12/2022

Wella Operations US LLC