

NIOXIN PRO CLINICAL SCALP RECOVERY- pyrithione zinc
Wella Operations US LLC

Drug Facts

Active ingredient

Pyrithione zinc 1% (purifying shampoo)

Pyrithione zinc 0.5% (moisturizing conditioner)

Pyrithione zinc 0.1% (scalp 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

PURIFYING SHAMPOO

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

SCALP SOOTHING SERUM

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

PURIFYING SHAMPOO

Inactive ingredients water, sodium laureth sulfate, PEG-3 distearate, sodium laureth-8 sulfate, sodium chloride, cocamidopropyl betaine, acrylates/steareth-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.

SCALP 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, utica 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 USA WITH IMPORTED PARTS

Dist. Wella Operations US LLC,

Calabasas, CA 91302

www.nioxin.com

nioxin® PRO CLINICAL

SCALP RECOVERY™ SYSTEM

FOR ANTI-DANDRUFF

FOR ITCHY, FLAKY SCALP

WITH PYRITHIONE ZINC

FOR ALL HAIR TYPES

CLINICALLY & DERMATOLOGICALLY TESTED

SCALP RECOVERY™
purifying shampoo
200 mL (6.7 FL OZ)

SCALP RECOVERY™
moisturizing conditioner
200 mL (6.7 FL OZ)

SCALP RECOVERY™
scalp soothing serum
100 mL (3.3 FL OZ)

22.22
[0.875]

53.2
[2.095]

nioxin® TOP SCALP RECOVERY® SYSTEM
PRO CLINICAL *Reads This Way* for anti-dandruff

#1 PROFESSIONAL BRAND FOR **THICKER, FULLER HAIR**²

nioxin®
— PRO CLINICAL —

SCALP RECOVERY® SYSTEM

FOR ANTI-DANDRUFF	<p>FOR ITCHY, FLAKY SCALP WITH PYRITHIONE ZINC</p> <p>FOR ALL HAIR TYPES</p> <p><i>Reads This Way</i></p>
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COMBATS DANDRUFF FROM THE 1ST USE

nioxin® PRO CLINICAL

SCALP RECOVERY®
purifying shampoo

FOR ANTI-DANDRUFF FOR ITCHY, FLAKY SCALP COMBATS DANDRUFF FROM THE 1ST USE WITH PYRITHIONE ZINC

200mL | 6.7FLOZ

nioxin® PRO CLINICAL

SCALP RECOVERY®
moisturizing conditioner

FOR ANTI-DANDRUFF FOR ITCHY, FLAKY SCALP COMBATS DANDRUFF FROM THE 1ST USE WITH PYRITHIONE ZINC

200mL | 6.7FLOZ

nioxin® PRO CLINICAL

SCALP RECOVERY®
scalp soothing serum

FOR ANTI-DANDRUFF FOR ITCHY, FLAKY SCALP COMBATS DANDRUFF FROM THE 1ST USE WITH PYRITHIONE ZINC

100mL | 3.3FLOZ

CLINICALLY & DERMATOLOGICALLY TESTED

200mL | 6.7FLOZ 200mL | 6.7FLOZ 100mL | 3.3FLOZ

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NIOXIN PRO CLINICAL SCALP RECOVERY

pyrithione zinc kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82157-010
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82157-010-99	1 in 1 CARTON; Type 1: Convenience Kit of Co-Package	12/19/2024	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE, PLASTIC	200 mL
Part 2	1 BOTTLE, PLASTIC	100 mL
Part 3	1 BOTTLE, PLASTIC	200 mL

Part 1 of 3

NIOXIN PRO CLINICAL SCALP RECOVERY MOISTURIZING CONDITIONER

pyrithione zinc lotion

Product Information

Item Code (Source)	NDC:82157-008
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Route of Administration	TOPICAL
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Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
SAGE (UNII: 065C5D077J)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
BETULA PUBESCENS LEAF (UNII: 84SOH00300)	
ACHILLEA MILLEFOLIUM (UNII: 2FXJ6SW4PK)	
FORMALDEHYDE/SODIUM NAPHTHALENESULFONATE COPOLYMER (3000 MW) (UNII: 90D834OZUI)	
STEARAMIDOPROPYL DIMETHYLAMINE (UNII: K7VEI00UFR)	

GLUTAMIC ACID (UNII: 3KX376GY7L)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
HEXYL CINNAMAL (UNII: 7X6O37OK2I)
LIMONENE, (+/-)- (UNII: 9MC3I34447)
MENTHA PIPERITA (PEPPERMINT) OIL (UNII: AV092KU4JH)
WATER (UNII: 059QF0KO0R)
CETYL ALCOHOL (UNII: 936JST6JCN)
CITRIC ACID (UNII: 2968PHW8QP)
CAMELLIA SINENSIS LEAF (UNII: W2ZU1RY8B0)
CARAMEL (UNII: T9D99G2B1R)
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)
YEAST, UNSPECIFIED (UNII: 3NY3SM6B8U)
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)
MALTODEXTRIN (UNII: 7CVR7L4A2D)
GERANIOL (UNII: L837108USY)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)
PROPYLPARABEN (UNII: Z8IX2SC1OH)
PANTHENOL (UNII: WW9CM0O67Z)
INOSITOL (UNII: 4L6452S749)
URTICA DIOICA LEAF (UNII: X6M0DRN46Q)
CELLULOSE GUM (UNII: K679OBS311)
GLUCOSE (UNII: 5SL0G7R0OK)
SODIUM BENZOATE (UNII: OJ245FE5EU)
DIMETHICONE (UNII: 92RU3N3Y1O)
MENTHA ARVENSIS LEAF OIL (UNII: 1AEY1M553N)
NIACINAMIDE (UNII: 25X51I8RD4)
CALCIUM PANTOTHENATE (UNII: 568ET80C3D)
EQUISETUM ARVENSE BRANCH (UNII: 1LOVKZ185E)
LACTIC ACID (UNII: 33X04XA5AT)
BIOTIN (UNII: 6S06U10H04)
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)
ETHOXYDIGLYCOL (UNII: A1A1I8X02B)
BENZYL ALCOHOL (UNII: LKG8494WBH)
METHYLPARABEN (UNII: A2I8C7HI9T)
ROSEMARY (UNII: IJ67X351P9)
TARTARIC ACID (UNII: W4888I119H)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82157-008-20	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

Part 2 of 3**NIOXIN PRO CLINICAL SCALP RECOVERY SCALP SOOTHING SERUM**

pyrithione zinc lotion

Product Information**Item Code (Source)** NDC:82157-009**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
HEXYL CINNAMAL (UNII: 7X6O37OK2I)	
BENZYL SALICYLATE (UNII: WAO5MKN9TU)	
CAMEL (UNII: T9D99G2B1R)	
GLYCERYL STEARATE (UNII: 230OU9XXE4)	
GLUCOSE (UNII: 5SL0G7R0OK)	
YEAST, UNSPECIFIED (UNII: 3NY3SM6B8U)	
CETEARYL ALCOHOL (UNII: 2DMT128M1S)	
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
URTICA DIOICA LEAF (UNII: X6M0DRN46Q)	
BHT (UNII: 1P9D0Z171K)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
STEARAMIDOPROPYL DIMETHYLAMINE (UNII: K7VEI00UFR)	
CALCIUM PANTOTHENATE (UNII: 568ET80C3D)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
ETHOXYDIGLYCOL (UNII: A1A1I8X02B)	
CITRIC ACID (UNII: 2968PHW8QP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
GERANIOL (UNII: L837108USY)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
EQUISETUM ARVENSE BRANCH (UNII: 1L0VKZ185E)	
OLEYL ALCOHOL (UNII: 172F2WN8DV)	
PANTHENOL (UNII: WW9CM0O67Z)	
TARTARIC ACID (UNII: W4888I119H)	

STEARYL ALCOHOL (UNII: 2KR89I4H1Y)
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)
ALPHA-ISOMETHYL IONONE (UNII: 9XP4LC555B)
SILICA (UNII: ETJ7Z6XBU4)
SODIUM BENZOATE (UNII: OJ245FE5EU)
BETULA PUBESCENS LEAF (UNII: 84SOH00300)
CETYL ALCOHOL (UNII: 936JST6JCN)
HYDROXYETHYLCELLULOSE (UNII: T4V6TWG28D)
CELLULOSE GUM (UNII: K679OBS311)
LACTIC ACID (UNII: 33X04XA5AT)
BENZYL ALCOHOL (UNII: LKG8494WBH)
ROSEMARY (UNII: IJ67X351P9)
ACHILLEA MILLEFOLIUM (UNII: 2FXJ6SW4PK)
CAMELLIA SINENSIS LEAF (UNII: W2ZU1RY8B0)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
DISODIUM PHOSPHATE (UNII: 22ADO53M6F)
LIMONENE, (+/-)- (UNII: 9MC3I34447)
PROPYLPARABEN (UNII: Z8IX2SC1OH)
MENTHA PIPERITA (PEPPERMINT) OIL (UNII: AV092KU4JH)
PEG-2M (UNII: V46Y6OJ5QB)
SODIUM PHOSPHATE (UNII: SE337SVY37)
INOSITOL (UNII: 4L6452S749)
MENTHA ARVENSIS LEAF OIL (UNII: 1AEY1M553N)
BIOTIN (UNII: 6SO6U10H04)
SAGE (UNII: 065C5D077J)
DISTEARYLDIMONIUM CHLORIDE (UNII: OM9573ZX3X)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
MALTODEXTRIN (UNII: 7CVR7L4A2D)
WATER (UNII: 059QF0KO0R)
NIACINAMIDE (UNII: 25X51I8RD4)
FORMALDEHYDE/SODIUM NAPHTHALENESULFONATE COPOLYMER (3000 MW) (UNII: 90D834OZUI)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82157-009-01	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 Drug	M032	12/19/2024	

Part 3 of 3

NIOXIN PRO CLINICAL SCALP RECOVERY PURIFYING

pyrithione zinc shampoo

Product Information

Item Code (Source) NDC:82157-007

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
PANTHENOL (UNII: WW9CM0O67Z)	
MAGNESIUM LAURETH-8 SULFATE (UNII: 2OTJ9LF5UA)	
YEAST, UNSPECIFIED (UNII: 3NY3SM6B8U)	
CALCIUM PANTOTHENATE (UNII: 568ET80C3D)	
TARTARIC ACID (UNII: W4888I119H)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
SAGE (UNII: 065C5D077J)	
MAGNESIUM OLETH SULFATE (UNII: LCQ4WP3DTL)	
PEG-3 DISTEARATE (UNII: 8420ECX438)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
BETULA PUBESCENS LEAF (UNII: 845OH00300)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
GLUCOSE (UNII: 5SL0G7R0OK)	
SODIUM LAURETH-8 SULFATE (UNII: YP8U3694P0)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
FORMALDEHYDE/SODIUM NAPHTHALENESULFONATE COPOLYMER (3000 MW) (UNII: 90D834OZUI)	
BIOTIN (UNII: 6S06U10H04)	
ROSEMARY (UNII: IJ67X351P9)	
SODIUM OLETH SULFATE (UNII: 3MX3FTR4XP)	
WATER (UNII: 059QF0KO0R)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
URTICA DIOICA LEAF (UNII: X6M0DRN46Q)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
INOSITOL (UNII: 4L6452S749)	
LIMONENE, (+/-)- (UNII: 9MC3I34447)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CITRIC ACID (UNII: 2968PHW8QP)	
ACHILLEA MILLEFOLIUM (UNII: 2FXJ6SW4PK)	
HEXYL CINNAMAL (UNII: 7X6O37OK2I)	
ACRYLATES/STEARETH-20 METHACRYLATE COPOLYMER (UNII: EPA1872R1N)	

GERANIOL (UNII: L837108USY)
NIACINAMIDE (UNII: 25X51I8RD4)
LACTIC ACID (UNII: 33X04XA5AT)
CAMELLIA SINENSIS LEAF (UNII: W2ZU1RY8B0)
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)
MENTHA PIPERITA (PEPPERMINT) OIL (UNII: AV092KU4JH)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)
ETHOXYDIGLYCOL (UNII: A1A1I8X02B)
MAGNESIUM LAURETH SULFATE (UNII: UKW9G007TZ)
DMDM HYDANTOIN (UNII: BYR0546TOW)
SODIUM HYDROXIDE (UNII: 55X04QC32I)
CELLULOSE GUM (UNII: K679OBS311)
POLYQUATERNIUM-10 (400 MPA.S AT 2%) (UNII: HB1401PQFS)
EQUISETUM ARVENSE BRANCH (UNII: 1LOVKZ185E)
MENTHA ARVENSIS LEAF OIL (UNII: 1AEY1M553N)
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)
CARAMEL (UNII: T9D99G2B1R)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82157-007-20	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 Drug	M032	12/19/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M032	12/19/2024	

Labeler - Wella Operations US LLC (117781338)

Establishment

Name	Address	ID/FEI	Business Operations
kdc/one Chatsworth, Inc.		118542196	manufacture(82157-010)