NIOXIN SCALP RECOVERY MEDICATING CLEANSER- pyrithione zinc lotion
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 ®

Medicating Cleanser

Drug Facts

Active ingredient

Pyrithione Zinc 0.5%

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

Directions

- 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.

Inactive ingredients

WATER, STEARYL ALCOHOL, CETYL ALCOHOL, STEARAMIDOPROPYL DIMETHYLAMINE, DIMETHICONE, GLUTAMIC ACID, BENZYL ALCOHOL, PHENOXYETHANOL, FRAGRANCE, PROPYLPARABEN, METHYLPARABEN, CITRIC ACID, MENTHA PIPERITA (PEPPERMINT) OIL, MENTHA ARVENSIS LEAF OIL, MENTHOL, YEAST EXTRACT, CAMELLIA SINENSIS LEAF EXTRACT, LECITHIN, PPG-26-BUTETH-26, SACCHAROMYCES/MAGNESIUM FERMENT, DIMETHYL ISOSORBIDE, PEG/PPG-18/18 DIMETHICONE, ETHOXYDIGLYCOL, CARNITINE HCL, 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 - 200 mL Bottle Label

NIOXIN ®
SCALP RECOVERY ®

For a dry, itchy scalp

PYRITHIONE ZINC
DANDRUFF
CONDITIONER

MOISTURIZING
CONDITIONER

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

99864275

200 mL (6.76 FL OZ)

NIOXIN SCALP RECOVERY MEDICATING CLEANSER

pyrithione zinc lotion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69282-007
Route of Administration	TOPICAL		

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

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
CETYL ALCOHOL (UNII: 936JST6JCN)	

STEARAMIDOPROPYL DIMETHYLAMINE (UNII: K7VEI00UFR)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
GLUTAMIC ACID (UNII: 3KX376GY7L)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
MENTHA ARVENSIS LEAF OIL (UNII: 1AEY1M553N)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
YEAST, UNSPECIFIED (UNII: 3NY3SM6B8U)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
PPG-26-BUTETH-26 (UNII: 2II1K6TZ4P)	
DIMETHYL ISOSORBIDE (UNII: SA6A6V432S)	
PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794)	
DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A1I8X02B)	
LEVOCARNITINE HYDROCHLORIDE (UNII: J3Y5E6IKS3)	
RICE BRAN (UNII: R60QEP13IC)	
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	
ACACIA (UNII: 5C5403N26O)	
UBIDECARENONE (UNII: EJ27X76M46)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69282-007-50	1 in 1 CARTON	07/01/2016	
1		50 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:69282-007-20	200 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/01/2016	
3	NDC:69282-007-10	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/01/2016	

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(69282-007)