

**NIOXIN SCALP RECOVERY MEDICATING CLEANSER- 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[®]

Medicating Cleanser

Drug Facts

Active ingredient

Pyrithione Zinc **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

- 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, SODIUM LAURETH SULFATE, SODIUM LAURYL SULFATE, COCAMIDE MEA, ZINC CARBONATE, GLYCOL DISTEARATE, DIMETHICONE, CETYL ALCOHOL, GUAR HYDROXYPROPYLTRIMONIUM CHLORIDE, SODIUM XYLENESULFONATE, MAGNESIUM SULFATE, SODIUM CHLORIDE, SODIUM BENZOATE, FRAGRANCE, DMDM HYDANTOIN, MENTHA PIPERITA (PEPPERMINT) OIL, MENTHOL, MENTHA ARVENSIS LEAF OIL, MAGNESIUM CARBONATE HYDROXIDE, BENZYL ALCOHOL, CAMELLIA SINENSIS LEAF EXTRACT, YEAST EXTRACT, LECITHIN, SACCHAROMYCES/MAGNESIUM FERMENT, BIOTIN/FOLIC ACID/CYANOCOBALAMIN/NIACINAMIDE/PANTOTHENIC ACID/PYRIDOXINE/RIBOFLAVIN/THIAMINE/YEAST POLYPEPTIDES, SACCHAROMYCES/IRON FERMENT, SACCHAROMYCES/COPPER FERMENT, SACCHAROMYCES/SILICON FERMENT, SACCHAROMYCES/ZINC FERMENT.

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 AND
SEBORRHEIC
DERMATITIS
SHAMPOO

MEDICATING
CLEANSER

100% FLAKE FREE
ELIMINATION OF
VISIBLE FLAKES WITH
REGULAR USE

99405984

200 mL (6.76 FL OZ)



NIOXIN SCALP RECOVERY MEDICATING CLEANSER

pyrithione zinc lotion/shampoo

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69282-005
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
WATER (UNII: 059QF0KO0R)	
SODIUM LAURETH-3 SULFATE (UNII: BPV390UAP0)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
COCO MONOETHANOLAMIDE (UNII: C80684146D)	
ZINC CARBONATE (UNII: EQR32Y7H0M)	

GLYCOL DISTEARATE (UNII: 13W7MDN21W)
DIMETHICONE (UNII: 92RU3N3Y1O)
CETYL ALCOHOL (UNII: 936JST6JCN)
GUAR HYDROXYPROPYLTRIMONIUM CHLORIDE (1.7 SUBSTITUENTS PER SACCHARIDE) (UNII: B16G315W7A)
SODIUM XYLENESULFONATE (UNII: G4LZF950UR)
MAGNESIUM SULFATE, UNSPECIFIED FORM (UNII: DE08037SAB)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
SODIUM BENZOATE (UNII: OJ245FE5EU)
DMDM HYDANTOIN (UNII: BYR0546TOW)
PEPPERMINT OIL (UNII: AV092KU4JH)
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)
MENTHA ARVENSIS LEAF OIL (UNII: 1AEY1M553N)
MAGNESIUM CARBONATE HYDROXIDE (UNII: YQO029V1L4)
BENZYL ALCOHOL (UNII: LKG8494WBH)
GREEN TEA LEAF (UNII: W2ZU1RY8B0)
YEAST, UNSPECIFIED (UNII: 3NY3SM6B8U)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69282-005-50	1 in 1 CARTON	07/01/2016	
1		50 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:69282-005-20	200 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/01/2016	
3	NDC:69282-005-10	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(69282-005)