

LIFECCELL WOMENS- pyrithione zinc liquid
AmWiner & Raphe Holdings 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.

Active Ingredient

Pyrithione Zinc

Purpose

Seborrheic dermatitis

Uses

- Relieves scalp itching, irritation, redness, flaking and scaling due to seborrheic dermatitis.
- Helps eliminate recurrence of seborrheic dermatitis

Warnings

For external use only

Ask a doctor before use if condition covers a large area.

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 the product as directed.

Keep out of reach of children. If swallowed, get medical help, or contact a Poison Control Center right away.

Directions

Apply to affected area one ml two times daily or as directed by the physician

Other information

- Store at 59° to 77°F (15° to 25°C)

Inactive ingredients

Purified Water, Propylene Glycol, Vitamin B5, Minoxidil, Green Tea, Biotin

Questions or Comments

Product label



**2% MINOXIDIL
TOPICAL SOLUTION USP
HAIR REGROWTH TREATMENT**

Reactivates Hair Follicles
To Stimulate Regrowth

Unscented
Topical Solution

**One Month Supply
60mL (2fl oz)**

Drug Facts
Active ingredient-----Purpose
Pyrrithione Zinc 0.1%-----Seborrheic Dermatitis

Uses
• Relieves scalp itching, irritation, redness, flaking and scaling due to seborrheic dermatitis.
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Keep out of reach of children. If swallowed, get medical help, or contact a Poison Control Center right away.

Directions
Apply to affected area one ml two times daily or as directed by the physician

Other information
Store at 59° to 77°F (15° to 25° C)

Inactive ingredients
Purified Water, Propylene Glycol, Pantothenic Acid (Vitamin B5), Minoxidil, Green Tea, Biotin

Questions or Comments:
support@lifecellskin.com

Distributed By: South Beach Skincare Inc.
701 N Federal Hwy 4th Floor Web: Lifecellskincare.com
Hallandale Beach, FL 33009 Phone: 1 866-978-5848
Lot#: AM2-92250K Exp: 08/27

LIFECCELL WOMENS

pyrrithione zinc liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82627-003
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
WATER (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PANTHENOL (UNII: WW9CM0067Z)	

MINOXIDIL (UNII: 5965120SH1)

GREEN TEA LEAF (UNII: W2ZU1RY8B0)

BIOTIN (UNII: 6SO6U10H04)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82627-003-01	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/01/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part358H	11/01/2022	

Labeler - AmWiner & Raphe Holdings LLC (113433590)

Establishment

Name	Address	ID/FEI	Business Operations
AmWiner & Raphe Holdings LLC		113433590	manufacture(82627-003)

Revised: 11/2022

AmWiner & Raphe Holdings LLC