

RAPHE PHARMACEUTIQUE BIOTIN GREEN TEA PRO VITAMIN B5- 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

Inactive ingredients

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

Other information

- Store at 59° to 77°F (15° to 25°C)

Product Label

RAPHE PHARMACEUTIQUE LABORATORIES
MINOXIDIL PRODUCT MANUFACTURER

CYCLONOXIL SOLUTION
2% SOLUTION

Hair Thickening Liquid
Stimulates Hair Growth
Anti-Fungal Anti-Hair Loss

BIOTIN
GREEN TEA
PRO-VITAMIN B5

2 FL OZ/60ML

Drug Facts Active ingredient-----Purpose PyrrithioneZinc 0.1%-----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, Pantothenic Acid (Vitamin B5), Minoxidil, Green Tea, Biotin
Questions or Comments: Call 469-428-5508

AmWiner Raphe Holdings LLC
Dallas TX 75243
Web: Healthcareprivatelabel.com
Made in the United States

RAPHE PHARMACEUTIQUE BIOTIN GREEN TEA PRO VITAMIN B5
pyrrithione zinc liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82627-001
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: WW9CM0O67Z)			
MINOXIDIL (UNII: 5965120SH1)			
GREEN TEA LEAF (UNII: W2ZU1RY8B0)			
BIOTIN (UNII: 6SO6U10H04)			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82627-001-01	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/01/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part358H	09/01/2022	

Labeler - AmWiner & Raphe Holdings LLC (113433590)

Establishment

Name	Address	ID/FEI	Business Operations
AmWiner & Raphe Holdings LLC		113433590	manufacture(82627-001)

Revised: 9/2022

AmWiner & Raphe Holdings LLC