

**ADVANCED HERBAL CARE FOR THINNING-DAMAGED HAIR- pyrithione zinc shampoo**  
**B'IOTA Laboratories**

*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.*

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Pyrithione Zinc 1.5%

Pyrithione Zinc 1.5%.....Antidandruff

Helps eliminate and reduces the recurrence of scalp itching, irritation, redness, flaking and scaling associated with dandruff.

**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**

- apply a tablespoon of shampoo to wet hair and gently massage the scalp with fingertips for 1.5 to 2 minutes and rinse well
- for best results use at least twice a week or as directed by a doctor

Store away from direct sunlight

WATER/AQUA, SODIUM LAURETH SULFATE, SODIUM CHLORIDE, COCAMIDOPROPYL BETAINE, HERBAL BIOCOMPLEX B11 (URTICA URENS LEAF EXTRACT, URTICA DIOICA (NETTLE) EXTRACT, CHAMOMILLA RECUTITA (MATRICARIA) FLOWER EXTRACT, ACHILLEA MILLEFOLIUM EXTRACT, CERATONIA SILIQUA (CAROB) FRUIT EXTRACT, EQUISETUM ARVENSE EXTRACT), ZINC PYRITHIONE, BENZYL ALCOHOL, FRAGRANCE/PARFUM, CARBOMER, PROPYLENE GLYCOL, HYDROXYPROPYL GUAR HYDROXYPROPYLTRIMONIUM CHLORIDE, AMODIMETHICONE, TETRASODIUM EDTA, MEL, C11-15 PARETH-7, LAURETH-9, BUTYLPHENYL METHYLPROPIONAL, GLYCERIN, COUMARIN, HYDROXYISOHEXYL 3-CYCLOHEXENE CARBOXALDEHYDE, TRIDECETH-12, VITIS VINIFERA SEED EXTRACT, METHYLCHLOROISOTHIAZOLIN, METHYLISOTHIAZOLINONE

Toll Free 1-855-246-8291 Monday through Friday, 9am-5pm

B'IOTA Botanicals Herbal Care Experts

Advanced Herbal Care Daily Care Shampoo

- Dermatologist tested formula for thinning-damaged hair that revitalizes the appearance of hair while increasing volume and thickness for fuller and stronger looking hair
- Strengthens hair
- Hypoallergenic
- Perfect for women & men
- Extracts from plants
- No known side effects
- Safe for all hair types & textures

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**Clinically Tested\***

**97%** More than 97% of subjects reported thicker, fuller and stronger looking hair when using shampoo and serum combined.\*

**83%** More than 83% of subjects reported thicker, fuller and stronger looking hair when using only BIOTA Herbal Shampoo.\*

\*Results of a 6-month, placebo-controlled, independent clinical study using BIOTA Botanicals Advanced Herbal Care Shampoo and Leave-In Serum.

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**For best results, use daily and in conjunction with BIOTA Botanicals Advanced Herbal Conditioner and Leave-In Serum****Directions for use**

Apply BIOTA Botanicals Herbal Shampoo for thinning-damaged hair to wet hair. Gently massage into the scalp for 1 1/2-to-2 minutes. Rinse well. Repeat if desired.

Distributed by:

BIOTA International LLC

369 Lexington Avenue, New York, NY 10017

Product of Turkey

[www.biotaUSA.com](http://www.biotaUSA.com)

Toll Free 855-246-8291

**WHAT CAUSES THINNING-DAMAGED HAIR?**

It's completely natural for hair to thin over time. Changes in hair volume can happen for many reasons including diet, stress, over-treatment, over-styling and the sun among other causes.

**WHAT IS ADVANCED HERBAL CARE?**

BIOTA Botanicals Advanced Herbal Care is our line of Shampoos, Conditioner and Leave-In Serum for thinning-damaged hair. The rich, herbal blends found in BIOTA Botanicals Advanced Herbal Care are derived from ingredients found in nature, many of which date back to ancient Mesopotamia and have long been part of European beauty secrets and body care rituals from the distant past.

All of our hair care products are made with an exclusive combination of herbal extracts. BIOTA Botanicals Advanced Herbal Care was specifically formulated to help combat and bring new hope to those experiencing thinning-damaged hair. Regular and continued use revitalizes the appearance of hair and

- Promotes Stronger
- Nourishes Healthier
- Encourages Thicker & Fuller Looking Hair

BIOTA Botanical Laboratories, the leading and trusted herbal care experts, is committed to marrying science with nature to create the exclusive, clinically tested blend found in Advanced Herbal Care.

**BIOTA BOTANICALS AROUND THE WORLD**

Loyal BIOTA customers around the world tell us how effective our products are. Now you can get to know the rich, luxurious and aromatic experience of our plant-based, easy-to-use Advanced Herbal Care Shampoo, Conditioner and Leave-In Serum for thinning-damaged hair.

**NEW HOPE FOR FULLER, STRONGER AND THICKER LOOKING HAIR**

All of BIOTA Botanicals Advanced Herbal Care products contains our exclusive, scientifically formulated Herbal BioComplex B11, a clinically tested combination of herbal extracts with naturally occurring minerals and essential fatty acids that work by nourishing the scalp.

This powerful blend brings new hope to those who want to combat thinning- damaged hair, helping in the fight to maintain and encourage stronger, more resilient hair and can only be found in BIOTA Botanicals' products.

**HERBAL CARE,  
DERMATOLOGIST TESTED**

- **Hypoallergenic**
- **Paraben Free**
- **Phthalate Free**

Dandruff Shampoo

**B'IOTA BOTANICALS**

**ADVANCED HERBAL CARE**

**for thinning-damaged hair**

- Promotes Stronger
- Nourishes Healthier
- Encourages Thicker & Fuller Looking Hair

Clinically Tested 97% reported Stronger, Thicker, Fuller Looking Hair\*

**☐Daily Care Shampoo**

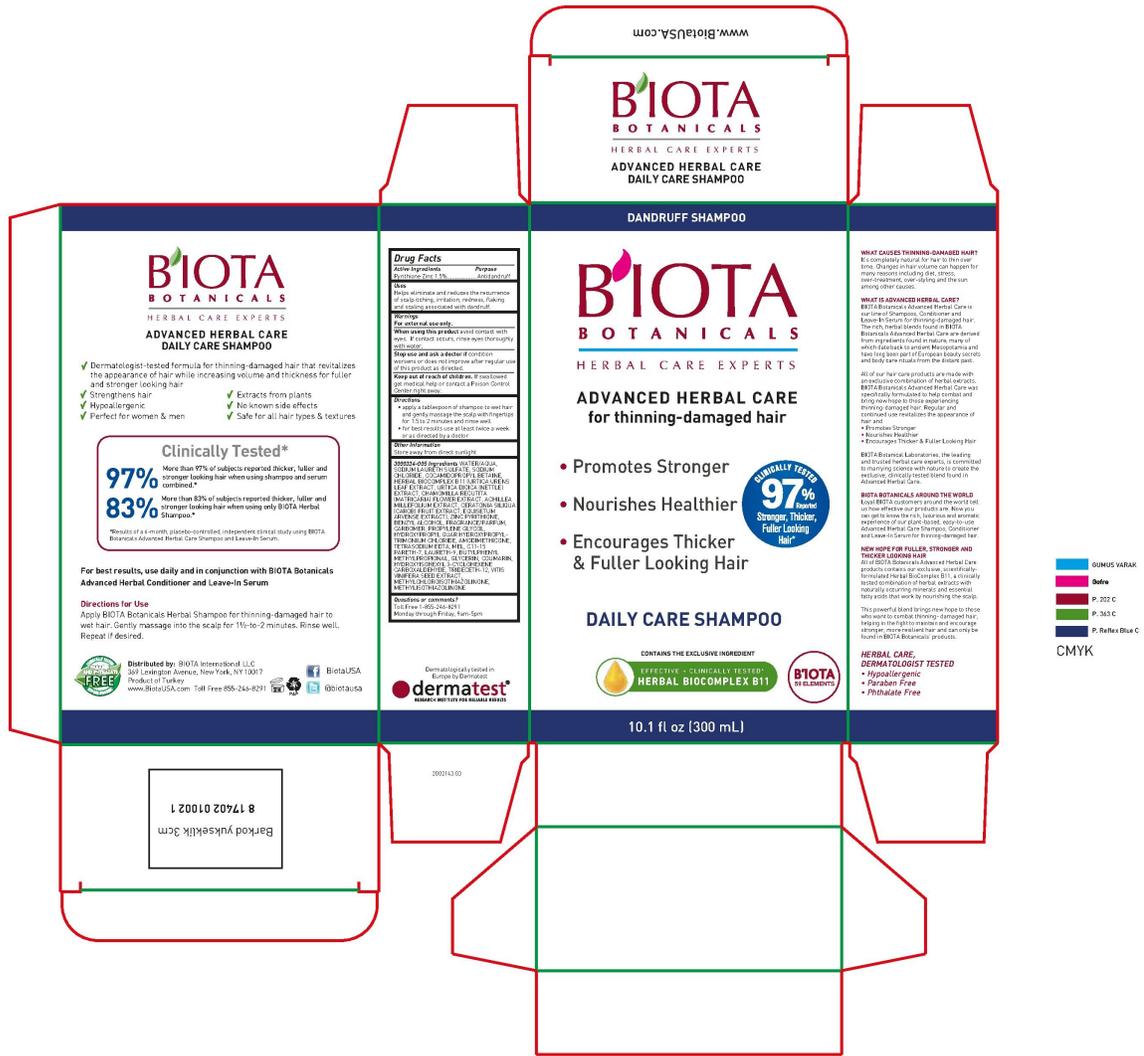
Contains the exclusive ingredient

Effective - Clinically Tested\*

**HERBAL BIOCOMPLEX B11**

B'IOTA 59 Elements

**10.1 fl oz (300 mL)**



## ADVANCED HERBAL CARE FOR THINNING-DAMAGED HAIR

pyrithione zinc shampoo

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:23637-002
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PYRITHIONE ZINC (UNII: R953O2RHZ5) (PYRITHIONE ZINC - UNII:R953O2RHZ5)	PYRITHIONE ZINC	0.15 g in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3011KX)	

URTICA URENS LEAF (UNII: 0DCW2P163M)
URTICA DIOICA ROOT (UNII: J8HE8A6E5T)
CHAMOMILE (UNII: FGL3685T2X)
ACHILLEA MILLEFOLIUM (UNII: 2FXJ6SW4PK)
CAROB (UNII: 5MG5Z946UO)
EQUISETUM ARVENSE TOP (UNII: 1DP6Y6B65Z)
BENZYL ALCOHOL (UNII: LKG8494WBH)
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
HYDROXYPROPYLTRIMONIUM CHLORIDE FRAGMENT (UNII: N30M4819DB)
EDETATE SODIUM (UNII: MP1J8420LU)
HONEY (UNII: Y9H1V576FH)
C11-15 PARETH-7 (UNII: 261HPE0IS3)
POLIDOCANOL (UNII: 0AWH8BFG9A)
BUTYLPHENYL METHYLPROPIONAL (UNII: T7540GJV69)
GLYCERIN (UNII: PDC6A3C0OX)
COUMARIN (UNII: A4VZ22K1WT)
HYDROXYISOHEXYL 3-CYCLOHEXENE CARBOXYALDEHYDE (UNII: QUE43B9Z2Q)
TRIDECETH-12 (UNII: YFY3KG5Y7O)
VITIS VINIFERA SEED (UNII: C34U15ICXA)
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:23637-002-01	1 in 1 CARTON	01/16/2018	
1		300 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part358H	01/16/2018	

**Labeler** - BIOTA Laboratories (968738240)

**Registrant** - BIOTA Laboratories (968738240)

Establishment			
Name	Address	ID/FEI	Business Operations
BIOTA BITKISEL ILAC VE KOZMETIK LABORATUARLARI TICARET A S		566215073	manufacture(23637-002)