

**BIOKERA - pyrithione zinc lotion/shampoo**  
**SALERM COSMETICA PROFESIONAL, S.A.**

*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.*

-----

**Drug Facts**

Inactive Ingredients: Water, Propylene Glycol, Cetyl Alcohol,  
Glycerin, Cetrimonium Chloride, Cyclopentasiloxane, Linum Usitattisium  
(Linseed) Seed oil, Amomethicone,  
Polyquaternum 11, Salicylic Acid, Citric Acid,  
Diazolidinyl Urea, Disodium Edta, Trideceth 12, Sodium Hydroxide,  
Iodopropynyl Butylcarbamate, Fragrance

Active Ingredient

Pyrithione Zinc 0,5 %

Purpose

Anti-dandruff

Keep this and all drugs out of  
reach of children.

If swallowed, get medical help or contact a Poison Control  
Center right away

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

Directions

-For the best results use at least twice a week or as directed  
by a doctor.

-After washing, apply the product to the hair without  
touching the scalp. Comb to distribute evenly and leave in to act for a few

minutes. Rinse with warm water and proceed to styling.

Questions or comments?

www.salerm.com - 0034 93 860 81 11



## BIOKERA

pyrithione zinc lotion/shampoo

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59538-002
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PYRITHIONE ZINC (UNII: R953O2RHZ5) (PYRITHIONE ZINC - UNII:R953O2RHZ5)	PYRITHIONE ZINC	.5 g in 10 g

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERIN (UNII: PDC6A3C0OX)	
CETRIMONIUM CHLORIDE (UNII: UC9PE95IBP)	
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
LINSEED OIL (UNII: 84XB4DV00W)	
AMODIMETHICONE (800 CST) (UNII: 363Z2T48P7)	
POLYQUATERNIUM-11 (1000000 MW) (UNII: 0B44BS5IJS)	
HEXYL SALICYLATE (UNII: 8F78EY72YL)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
TRIDECETH-12 (UNII: YFY3KG5Y7O)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59538-002-02	1 in 1 CARTON	08/01/2013	
1		196 g 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	08/01/2013	

**Labeler** - SALERM COSMETICA PROFESIONAL, S.A. (563418532)

Revised: 7/2016

SALERM COSMETICA PROFESIONAL, S.A.