

**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.*

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**Drug Facts**

Inactive Ingredients: Water, Sodium Laureth Sulfate,  
Cocamidopropyl Betane, Acrylates Copolymer, Fragrance,  
Linum Usitatissimum (Linseed) Seed Oil, Salicylic Acid,  
Polyquaternum 7, Laureth 4, Glycol Distearate, Cocamide  
Mipa, Undecylenamidopropyltrimonium Methosulfate,  
Propylene Glycol, Sodium Hydroxide, Sodium Chloride,  
Diazolidinyl Urea, Methylsulfathiazoline, Iodopropynol  
Butylcarbamate, Lactic Acid, Alpha Isomethylionine,  
Citronellol

Active Ingredient

Pyrithione Zinc 1,0 %

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.

-Wet the hair with warm water and apply the shampoo evenly throughout the first wash. Rinse and apply again. Leave in for a few minutes and rinse again,  
 Questions or comments?  
 www.salerm.com - 0034 93 860 81 11

**biokera**  
natura

SPECIFIC DANDRUFF  
**SHAMPOO**  
 CHAMPÚ  
 ESPECÍFICO  
 CASPA.  
**SHAMPOING**  
 SPÉCIFIQUE  
 PELLICULE

**Drug Facts**

Active ingredient(s):	Pyrisinolo
Other ingredient(s):	Trietanol

Use this product as directed. Do not use if you are allergic to any of the ingredients listed above.

**Warnings:**  
 For external use only.

**Directions:**  
 Wet hair and scalp thoroughly. Use only on wet hair. Massage into hair and scalp. Rinse thoroughly. Repeat if necessary.

**Other information:**  
 Keep this and all drugs out of reach of children. If swallowed, get medical help or call a poison control center.

**Contains:**  
 Pyrisinolo. For the treatment of dandruff and seborrheic dermatitis.

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**Use only as directed.**  
 For the treatment of dandruff and seborrheic dermatitis.

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300 ml e CONT. 306 g  
 NET WT. 10.8 OZ.

PL. RAGE  
 RECICLABLE

# BIOKERA

pyrithione zinc lotion/shampoo

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59538-001
Route of Administration	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PYRITHIONE ZINC (UNII: R953O2RHZ5) (PYRITHIONE ZINC - UNII:R953O2RHZ5)	PYRITHIONE ZINC	1 g in 10 g

## Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SODIUM LAURETH-3 SULFATE (UNII: BPV390UAP0)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
CHLOROPROPYLATE (UNII: GI03ROM7HQ)	
LINSEED OIL (UNII: 84XB4DV00W)	
HEXYL SALICYLATE (UNII: 8F78EY72YL)	
POLYQUATERNIUM-7 (70/30 ACRYLAMIDE/DADMAC; 160000 MW) (UNII: 0L414VCS5Y)	
LAURETH-4 (UNII: 6HQ855798J)	
GLYCOL DISTEARATE (UNII: 13W7MDN21W)	
COCO MONOISOPROPANOLAMIDE (UNII: 21X4Y0VTB1)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
3-iodo-1-propanol (UNII: 2FR2742AOL)	
LACTIC ACID (UNII: 33X04XA5AT)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59538-001-01	1 in 1 CARTON	08/01/2013	

1	300 g in 1 BOTTLE; Type 0: Not a Combination Product		
<b>Marketing Information</b>			
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph final	part358H	08/01/2013	

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

Revised: 7/2016

SALERM COSMETICA PROFESIONAL, S.A.