

**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



3.9 fl. oz. (113 ml) of shampoo. Shampooing procedure: Wet hair thoroughly with warm water. Apply shampoo to hair and massage into a lather. Rinse thoroughly. Repeat application. Leave on hair for a few minutes. Rinse again. Questions or comments? www.salerm.com - 0034 93 860 81 11

**Drug Facts**

Active Ingredient	Purpose
Hydrocortisone	Anti-Itch

(See important information about using and storing this medicine.)

**Warnings:**  
 For External Use Only

**What Other Medications Should I Tell My Doctor About?**  
 Tell your doctor about all the medicines you are taking, especially if you are taking any of the following:

**Do Not Use if You Have:**  
 A known allergy to hydrocortisone or any of the ingredients listed in the inactive ingredients section.

**Use with Caution if You Have:**  
 A history of tuberculosis, diabetes, glaucoma, cataracts, or other eye conditions.

**Do Not Use if You Are:**  
 Pregnant, planning to get pregnant, or breastfeeding.

**Use as Directed:**  
 Follow the directions on the label. Do not use for longer than 2 weeks unless directed by your doctor.

**Keep Out of Reach of Children:**  
 This medicine should be kept out of the reach of children.

**Other information:**  
 See important information about using this medicine on page 2 of the Patient Information Leaflet.

**Salerm COSMETICS**

1000 ml e CONT. 1020 g NET WT. 36 OZ.

www.salerm.com

ART. 3009

# BIOKERA

pyrithione zinc lotion/shampoo

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59538-004
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)	
CHLORO PROPYLATE (UNII: GI03ROM7HQ)	
LINSEED OIL (UNII: 84XB4DV00W)	
HEXYL SALICYLATE (UNII: 8F78EY72YL)	
POLYQUATERNIUM-7 (70/30 ACRYLAMIDE/DADMAC; 1600000 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
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1	NDC:59538-004-01	1 in 1 CARTON	09/01/2013	
1		1020 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		09/01/2013	

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

Revised: 7/2016

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