

**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, Alcohol Denat., Linum Usitatissimum,  
(Linseed) Seed Oil, Cetrimonium Chloride, Peg-40 Hydrogenated  
Castor Oil, Disodium Edta, Sodium Hydroxide, Fragrance

Active Ingredient

Pyrithione Zinc 0,1 %

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

-Apply to affected areas one to four time daily or as directed by a doctor.

-Firstly, wash the hair with anti-dandruff shampoo. Shake the phial well  
before use and then evenly apply the contents to the scalp.

Gently massage in with the fingertips using an outward and inward motion  
or allow to absorb and, without rinsing, style the hair in the usual manner.

Questions or comments?

www.salerm.com - 0034 93 860 81 11



<b>LINSEED OIL</b> (UNII: 84XB4DV00W)	
<b>CETRIMONIUM CHLORIDE</b> (UNII: UC9PE95IBP)	
<b>POLYOXYL 40 HYDROGENATED CASTOR OIL</b> (UNII: 7YC686GQ8F)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59538-003-03	6 in 1 CARTON	08/01/2013	
1		60 g in 1 VIAL; 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)

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