BIOKERA - pyrithione zinc lotion/s hampoo 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, Alcohol Denat., Linum Usitatissium,

(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

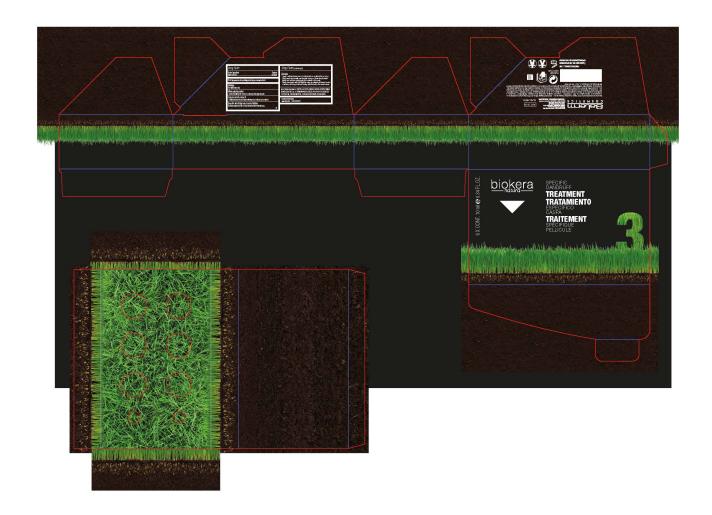
Directions

- -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



BIOKERA

pyrithione zinc lotion/shampoo

Droc	luct	Info	rmation
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Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59538-003
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Route of Administration TOPICAL

Active Ingredient/Active Moiety

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	Ingredient Name	Basis of Strength	Strength
DVDITHIONE ZINC (II	NII. D05303DH75) (DVDITHIONE ZINC - HNII.D05303DH75)	DVDITHIO NE ZINC	1 g in 10 g

Inactive Ingredients

indetive ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
ALCOHOL (UNII: 3K9958V90M)		
FLAX SEED (UNII: 4110 YT348 C)		

LINSEED OIL (UNII: 84XB4DV00W)	
CETRIMO NIUM CHLO RIDE (UNII: UC9 PE9 5 IBP)	
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	
EDETATE DISO DIUM (UNII: 7FLD9 1C8 6 K)	
SO DIUM HYDRO XIDE (UNII: 55X04QC32I)	

1	Packaging			
#	t 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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