

SPAI-SONS ALKALINE DRY-DANDRUFF- pyrithione zinc shampoo
SPAI-SONS PHARMACEUTICAL INTERNATIONAL COSMETICS

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.

SPAI-SONS SHAMPOO ALCALINO ANTI CASPA SECA / ALKALINE SHAMPOO DRY-DANDRUFF

This formula includes Zinc Pyrithione used to eliminate the agent causing dry dandruff and scalp drying.

USE: Hair washing and scalp affected by exfoliation, scales and dry dandruff

This product must be keep out reach of children.

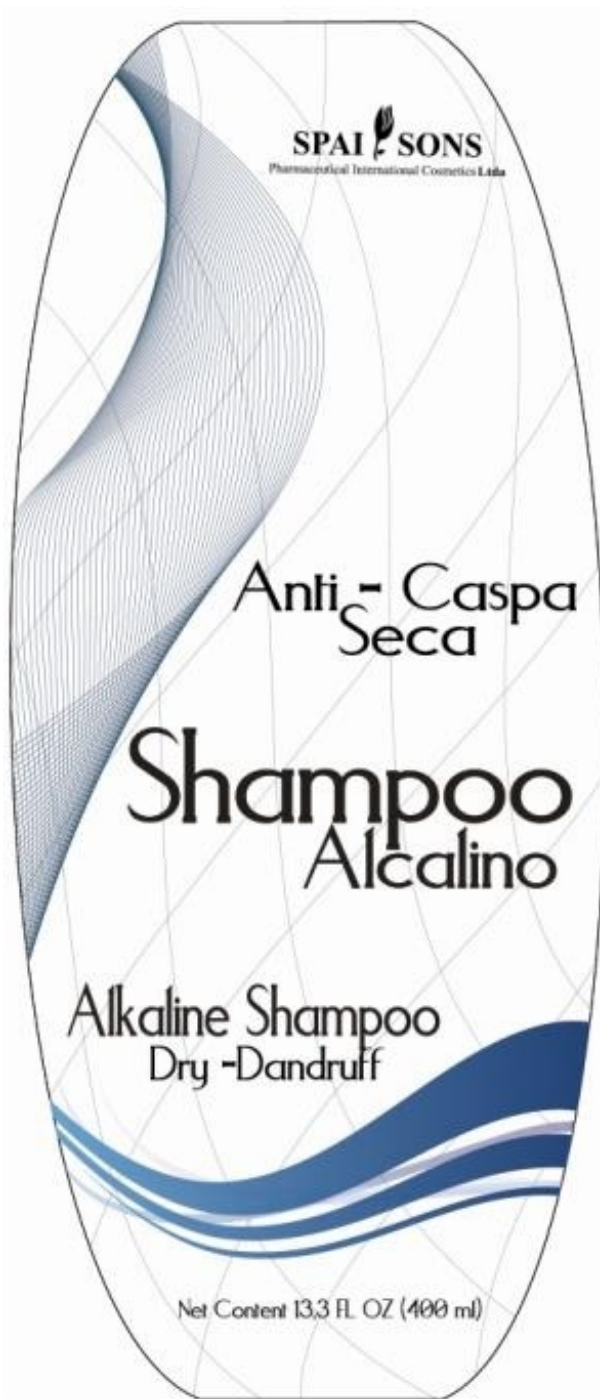
This product is for topical appplication. Wash the hair with the shampoo in the shower.

If this product is contact with eyes rinse immediately with water and consult your doctor

To wash daily during 8 or 10 weeks, soon interdaily use until the remission of the problem. This product is for topical application

This composition moisturizes and lubricate capillary dermis

IMAGE OF THE LABEL



Shampoo Alcalino / Anti-Caspa Seca

Esta formulación incluye: Piritionato de Zinc dirigido a eliminar el agente causal de la caspa seca (voladora) y el resecaimiento del cuero cabelludo. Su composición humecta y lubrica la dermis capilar.

USO: Lavado del cabello y cuero cabelludo con exfoliación, escamación o caspa seca.

MODO DE EMPLEO: Lavar diariamente durante 8 ó 10 semanas, luego uso interdiario hasta la remisión del problema.

INGREDIENTES: Agua, laureth sulfato sodico, acido tallow ftalico dihidrogenado amida, piritionato de zinc, cocamida DEA, Trietanolamina, PEG-120 Metilglucosa Diolate, Fragancia, Cloruro de Sodio, Metil Parabeno, Propil Parabeno, CI: 16255, CI: 42090.

Alkaline Shampoo / Dry Dandruff

This formula includes Zinc Pyrithione used to eliminate the agent causing dry dandruff and scalp drying. Its composition moisturizes and lubricates capillary dermis.

USE: Hair washing and scalp affected by exfoliation, scales and dry dandruff.

APPLICATION: to wash daily during 8 or 10 weeks, soon interdaily use until the remission of the problem.

INGREDIENTS: Water, sodium laureth sulfate, dihydrogenated tallow phthalic acid amide, zinc pyrithione, cocamide DEA, Triethanolamine, PEG-120 Methyl Glucose Diolate, Fragrance, Sodium Chloride, Methylparaben, Propylparaben, CI: 16255, CI:42090.



Manufactured by:

SPAI-SONS Pharmaceutical International Cosmetics.
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for American SPAI-SONS USA Corp. MIAMI, FL
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Distribuido por: All-Time Spai-sons Ecuatoriana/ Tulcan- Ecuador

Made in Bogotá Colombia.

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Lote Nº

SPAI-SONS ALKALINE DRY-DANDRUFF

pyrithione zinc shampoo

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66854-017
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 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
DIHYDROGENATED TALLOW PHTHALIC ACID AMIDE (UNII: 1R81RPY10G)	
COCO DIETHANOLAMIDE (UNII: 92005F972D)	
TROLAMINE (UNII: 9O3K93S3TK)	
PEG-120 METHYL GLUCOSE DIOLEATE (UNII: YM0K64F20V)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
PONCEAU 4R (UNII: Z525CBK9PG)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66854-017-01	210 mL in 1 BOTTLE		
2	NDC:66854-017-02	250 mL in 1 BOTTLE		
3	NDC:66854-017-03	400 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part358H	06/30/2012	

Labeler - SPAI-SONS PHARMACEUTICAL INTERNATIONAL COSMETICS (880172184)

Registrant - SPAI-SONS PHARMACEUTICAL INTERNATIONAL COSMETICS (880172184)

Establishment

Name	Address	ID/FEI	Business Operations
SPAI-SONS PHARMACEUTICAL INTERNATIONAL COSMETICS		880172184	analysis, label, manufacture, pack

Revised: 6/2012

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