SPAI-SONS ACID ANTI-DANDRUFF- sulfur shampoo SPAI-SONS PHARAMCUETICAL 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 ACIDO ANTI-CASPA / ACID SHAMPOO ANTI-DANDRUFF

This formula includes Biosulfur fluid, that is highest effectiveness for the scalp.

This fromula includes the active ingredient containing the highest effectiveness for the scalp called greasy dandruff

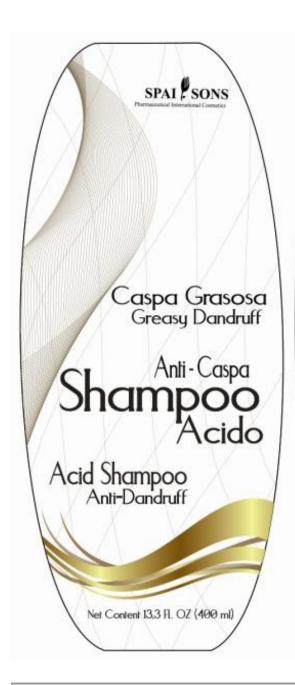
This product must be keep out reach of children

This product is for topical application. 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. The product is for topical application.

Its components make it tolerable for daily use or washing the scalp affected IMAGE OF THE LABEL



Shampoo Acido/ Anti-Caspa

Esta fórmula incluye el ingrediente activo de mayor efectividad en casos de caspa grasosa. Los componentes lo hacen tolerable en el uso diario o interdiario para el lavado del cabello y cuero cabelludo.

USO: Lavado diario del cabello y cuero cabelludo.

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

INGREDIENTES: Agua, Laureth Sulfato Sodico, Cocamidopropil Betaina, Acrilatos copolimero, Glicol Distearato, Cocamida MEA / Laureth-10, Bispiritiona, Fragancia, Pantenol, Polisorbato 80/Azufre, Trietanolamina, Acido Citrico, Metil Parabeno, Propil Parabeno, Cloruro de Sodio, CI 16255, CI 28440 / CI 19140.

Acid Shampoo / Anti-Dandruff

This formula includes the active ingredient containing the highest effectiveness for the scalp called greasy dandruff. Its components make it tolerable for daily use or washing the scalp affected.

USE: Daily hair and scalp washing .

APPLICATION: to wash daily during 8 or 10 weeks, soon interdaily use until the remission of the problem. INGREDIENTS: Water, sodium laureth sulfate, cocamidopropyl betaine, acrylates copolymer, glycol distearate, cocamide MEA / laureth-10, bispyrithione, fragrance, panthenol, polysorbate 80/sulfur, triethanolamine, cltric acid, methylparaben, propylparaben, sodium chloride, CI 16255, CI 28440 / CI 19140.



Manufactured by SPAI-SONS Pharmaceutical International Cosmedics Notif. Sanit. NSC1996CO33854 for American SPAI-SONS USA Corp MIAMI, FI (305)2086008

FI (305)2096008
Distribuido per: All-Time Spai-sens Ecustoriana' Tulcan-Ticuado Made in Begotá Colombia. Phone 4279090
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Lote №

SPAI-SONS ACID ANTI-DANDRUFF

sulfur shampoo

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:66854-021

Route of Administration TOPICAL

Active Ingredient/Active Moiety

	Ingredient Name	Basis of Strength	Strength
ı	SULFUR (UNII: 70 FD1KFU70) (SULFUR - UNII:70 FD1KFU70)	SULFUR	0.4 mL in 100 mL

Inactive Ingredients

Ingredient Name Strength

WATER (UNII: 059QF0KO0R)	
SODIUM LAURETH SULFATE (UNII: BPV390 UAP0)	
COCAMIDO PRO PYL BETAINE (UNII: 50 CF30 11 KX)	
GLYCOL DISTEARATE (UNII: 13W7MDN21W)	
SODIUM LAURETH SULFATE (UNII: BPV390 UAP0)	
SO DIUM LAURETH SULFATE (UNII: BPV390 UAP0)	
COCO MONOETHANOLAMIDE (UNII: C80684146D)	
LAURETH-10 (UNII: BD7AST04GA)	
DIPYRITHIO NE (UNII: 9L87N86R9A)	
PANTHENOL (UNII: WV9CM0O67Z)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
TROLAMINE (UNII: 903K93S3TK)	
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)	
METHYLPARABEN (UNII: A218 C7HI9 T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:66854-021-01	210 mL in 1 BOTTLE				
2	NDC:66854-021-02	250 mL in 1 BOTTLE				
3	NDC:66854-021-03	250 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 PHARAMCUETICAL INTERNATIONAL COSMETICS (880172184)

$\pmb{Registrant - \texttt{SPAI-SONS PHARMACEUTICAL INTERNATIONAL COSMETICS (880172184)}}$

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