

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 formula 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



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
SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)	SULFUR	0.4 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
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WATER (UNII: 059QF0KO0R)
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)
GLYCOL DISTEARATE (UNII: 13W7MDN21W)
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)
COCO MONOETHANOLAMIDE (UNII: C80684146D)
LAURETH-10 (UNII: BD7AST04GA)
DIPYRITHIONE (UNII: 9L87N86R9A)
PANTHENOL (UNII: WV9CM0O67Z)
POLYSORBATE 80 (UNII: 6OZP39ZG8H)
TROLAMINE (UNII: 9O3K93S3TK)
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)
METHYL PARABEN (UNII: A2I8C7HI9T)
PROPYL PARABEN (UNII: Z8IX2SC1OH)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
FD&C RED NO. 40 (UNII: WZB9127XOA)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)

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 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