SPAI-SONS PROLAC-VIT- biotin liquid SPAI-SONS PHARMACEUTICAL INTERNATIONAL COSMETICS

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

SPAI-SONS PROLAC-VIT

Biotin is a major component of the formulation acts to strengthen the hair follicle and prevents hair loss as well. It is nutrient for the hair root oxygenate the hair turn slowing the loss. Provides resilience and resistence to hair. Addition of biotin are other ingredient such as Asian Ginseng, Arginine, Zinc Gluconate, Niacinamide, Ornitine HCl, and Citrulline which help strengthen the hair follicle and produce a synergistic action on it.

Prolac-vit is a well balanced formula that helps the function and nutrition of hair root, resulting in abundant hair and neutralizing alopecia caused by lack and certain components, mistreatment or toxic agents.

This product must be keep out reach of children

This product is for topical application directly on the hair follicle.

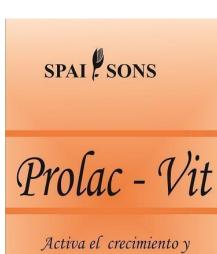
Avoid contact with eyes, if they do wash with water. If swallowed contact a physician immediately

Recommended use: thin or fragile, ill-treated hair, malnourished scalp or hair roots, Alopecia, hair loss due to cycle change.

Directions: must be applied directly to the scalp and then massage very gently until the product is absorbed

This is a liquid prepared with the technology needed to provide the hair follicle absorption of the active ingredients, plus inactive ingredients contribute to the regeneration of the hair fiber by providing a strengthening therefore. No adverse effects were seen with the use of this product as inactive ingredients do not cause skin hypersensivity.

IMAGE OF CARTON LABEL



retarda la caída del cabello

Prolac-vit

Stimulates hair growth and slows down hair loss

PROLAC-VIT is a well-balanced formula that helps the function and nutrition of the hair root, resulting in abundant hair and neutralizing loss caused by lack of certain components,

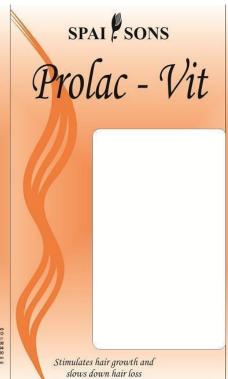
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RECOMMENDED USE: Thin or fragile hair, ill-treated hair, malnourished scalp or hair roots, Hair

mainourisned scaip or nair roots, thair loss due to cycle change. DIRECTIONS: PROLAC - VIT must be applied directly to the scalp and then massage ver gently until the product is absorbed. WARNINGS: keep out of reach of children. Do not ingest. Avoid contact with eves

with eyes. INGREDIENTS:water, alcohol, panax ginseng root extract, arginine, acetyl tyrosine, arctium majus root extract, hydrolyzed soy protein, polyquater-nium-11,PEG-12 dimethicone,calcium pantothenate,zinc gluconate ,niacina-mide , ornithine HCL ,citrulline , mide, ornitime HCL, citrulline glucosamine HCL, biotin, propylene glycol, amniotic fluid, hydrolyzed placental protein, triticum vulgare germ extract, polyquaternium-39, fragance, PEG-40 hydrogenated castor oil,acrylates/ C10-30 Alkyl acrylate crosspolymer,

triethanolamine,polysorbate 80,sulfur, panthenol, allantoin, methylparaben, diazolidinyl urea, menthol, CI 42090.

actured by SPAI-SONS Pharmaceutical Internations
Note: Sanit. NSOC-2581-00CD
Distribution per Al-Time Spai-sons Examination and the second for American SPAI-SONS USA Corp. Mile Propriet ST294
Made in Bogott Colombia. Prome: 420-80-80.
Made in Bogott Colombia. Prome: 420-80.
Made in Bogott Colombia.



Net Content 2.3 FL OZ

Prolac-vit

Activa el crecimiento y retarda la caída del cabello

PROLAC-VIT es una fórmula bien balanceada que favorece la nutrición y función del bulbo piloso, con lo que se logra abundancia de cabello y se neutraliza la pérdida por carencias, maltrato o agentes tóxicos. USO: Cabellos delgados y frágiles, cabellos maltratados, desnutrición del cuero cabelludo y bulbo piloso.

cuero cabelludo y bulbo piloso. Perdida del cabello por ciclo de

recambio.

MODO DE EMPLEO: PROLAC-VIT debe aplicarse directamente sobre el cuero cabelludo y hacer un suave masaje hasta que el producto penetre.

ADVERTENCIAS: Manténgase alejado del alcance de los niños. No se inglera. Evite el contacto con los ojos.

INGREDIENTES:

Agua, alcohol, extracto de raiz de panax ginseng, arginina, acetil tirosina, extracto de raiz de arctium majus, proteina hidrolizada de soya, policuaternio-11, PEG-12 dimeticona, pantotenato de calcio, gluconato de zinc, niacinamida, omitina HCL, biotina, propiena glicol, fluido amniotico, proteina placentaria hidrolizada, extracto de germen de triticum vulgare, policuaternio-39, fragancia, PEG-40 aceite de castor hidrogenado, acrilatos/C10-30 alquil acrilato crospolimencr, virteano lamina,

crospolimero, trietanolamina, polisorbato 80, azufre, pante-nol, alantoina, metil parabe-no, diazolidinil urea, mentol, CI42090.

70 ml

SPAI-SONS PROLAC-VIT

biotin liquid

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:66854-007
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
BIOTIN (UNII: 6SO6U10H04) (BIOTIN - UNII:6SO6U10H04)	BIOTIN	0.01 mg in 100 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	
ASIAN GINSENG (UNII: CUQ3A77YXI)	
ARGININE (UNII: 94ZLA3W45F)	
N-ACETYL-TYRO SINE (UNII: DA8 G6 10 ZO5)	
ARCTIUM LAPPA ROOT (UNII: 597E9BI3Z3)	
ASPARTIC ACID (UNII: 30 KYC7MIAI)	
HYDRO XYPRO LINE (UNII: RMB44WO89X)	
THREONINE (UNII: 2ZD004190S)	
SERINE (UNII: 452VLY9402)	
GLUTAMIC ACID (UNII: 3KX376GY7L)	

PROLINE (UNII: 9 DLQ4CIU6 V)
GLYCINE (UNII: TE7660 XO1C)
ALANINE (UNII: OF5P57N2ZX)
VALINE (UNII: HG18 B9 YRS7)
METHIO NINE (UNII: AE28 F7PNPL)
ISOLEUCINE (UNII: 04Y7590D77)
LEUCINE (UNII: GMW67QNF9C)
TYROSINE (UNII: 42HK56048U)
PHENYLALANINE (UNII: 47E5O 17Y3R)
HYDRO XYLYSINE (UNII: 2GQB349 IUB)
ORNITHINE (UNII: E524N2IXA3)
LYSINE (UNII: K3Z4F929H6)
HISTIDINE (UNII: 4QD397987E)
ARGININE (UNII: 94ZLA3W45F)
TRYPTO PHAN (UNII: 8 DUH1N11BX)
CYSTINE (UNII: 48 TCX9 A1VT)
POLYQUATERNIUM-11 (1000000 MW) (UNII: 0B44BS5IJS)
PEG-12 DIMETHICO NE (300 CST) (UNII: ZEL54N6W95)
CALCIUM PANTOTHENATE (UNII: 568ET80C3D)
ZINC GLUCO NATE (UNII: U6 WSN5SQ1Z)
NIACINAMIDE (UNII: 25X51I8RD4)
ORNITHINE HYDRO CHLO RIDE (UNII: HBK84K66XH)
CITRULLINE (UNII: 29 VT0 7BGDA)
GLUCO SAMINE HYDRO CHLO RIDE (UNII: 750 W5330 FY)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
AMNIOTIC FLUID (BO VINE) (UNII: P06X62O7E9)
HYDROLYZED PLACENTAL PROTEIN (BOVINE) (UNII: KR5CS6RBH9)
WHEAT GERM (UNII: YR3G369F5A)
POLYQUATERNIUM-39 (35/35/30 ACRYLIC ACID/ACRYLAMIDE/DADMAC; 1500000 MW) (UNII: EOD3UE785A)
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)
CARBOMER INTERPOLYMER TYPE A (55000 MPA.S) (UNII: 59TL3WG5CO)
TROLAMINE (UNII: 9O3K93S3TK)
POLYSORBATE 80 (UNII: 6OZP39ZG8H)
SULFUR (UNII: 70 FD1KFU70)
PANTHENOL (UNII: WV9CM0O67Z)
ALLANTO IN (UNII: 344S277G0Z)
METHYLPARABEN (UNII: A2I8C7HI9T)
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)
MENTHOL (UNII: L7T10EIP3A)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Product Characteristics			
Color	blue	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:66854-007-01	70 mL in 1 BOTTLE		
2 NDC:66854-007-02	10 mL in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		08/06/2012	

Labeler - SPAI-SONS PHARMACEUTICAL INTERNATIONAL COSMETICS (880172184)

Establishment				
Name	Address	ID/FEI	Business Operations	
SPAI-SONS PHARMACEUTICAL INTERNATIONAL COSMETICS		880172184	manufacture(66854-007), analysis(66854-007), label(66854-007), pack(66854-007)	

Revised: 8/2012 SPAI-SONS PHARMACEUTICAL INTERNATIONAL COSMETICS