SOLV X - salicylic acid shampoo Mediceutical Laboratories, LTD

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.

SOLV-X

Active ingredient

Salicylic Acid 1.8%

Purpose

anti-dandruff, anti-seborrheic, dermatitis

Uses

• Helps control and prevent flaking and itching associated with seborrheic dermatitis

Warnings

For external use only. If condition worsens or does not improve after regular use of this product as directed, discontinue and consult a physician. If condition covers a large area of the body, consult your physician before using this product.

Keep this and all drugs out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away. Avoid contact with eyes. If contact occurs, rinse eyes thoroughly with cool water.

Directions

For best results use daily or until condition is under control or as directed by a physician.

For maximum control use every time you shampoo.

- 1. Wet hair, massage liberal amount of Solv- X^{TM} onto the scalp and through the hair
- 2. Thoroughly rinse and repeat if desired
- 3. Apply Therapeutic TM Scalp and Hair Treatment Rinse for 1-2 minutes, thoroughly rinse.

Consult your Salon professional for additional Mediceuticals® scalp and hair treatments specifically tailored for your condition.

Inactive ingredients

Acetamide MEA, Ammonium Lauryl Sulfate, Ascorbic Acid (Vitamin C), Biotin, Blue 1 (Cl 42090), Camphor, Cocamide DEA, Cocamidopropyl Betaine, Cocoyl Sarcosine, Fragrance (Parfum), Hydrolyzed Glycosaminoglycans, Hydrolyzed Hair Keratin, Hydroxypropyl Methylcellulose, Inositol, Linoleic Acid, Linolenic Acid, Menthol, Panthenol, Polysorbate 80, SD Alcohol 40-B, Simmondsia Chinesis (Jojoba) Seed Oil, Sorbitol, Sodium Cocoyl Collagen Amino Acid, Tocopheryl Acetate, Triticum Vulgare (Wheat) Germ Oil, Water (Aqua), Wheat Germ Acid, Zinc Sulfate

 $SOLV-X^{TM}$

OILY SCALP AND HAIR TREATMENT SHAMPOO

MEDICEUTICALS®

Cruelty Free. Not tested on Animals.

Sold exclusively through fine Salons, Spas and Hair Restoration Clinics

Manufactured in the USA for:

Mediceutical Laboratories, LTD Fort Worth, Texas 76118

Customer Service: 1-800-433-2903

Mediceutical Europe B.V.

Kelvinstraat 61,2723 RJ Zoetermeer The Netherlands EU

Telephone: +31 79 3314029

NDC 5927950233 SOLV-X 33.8 fl oz

NDC 5927950206 SOLV-X 6 fl oz

NDC 5927950212 SOLV-X 12 fl oz

Front









SCALP THERAPIES

360 ml/12 fl. oz. e

Back

MEDICEU+ICALS

DERMATOLOGICAL SCALP, HAIR & SKIN SOLUTIONS

You have selected a Professional dermatological treatment specifically developed for treating a broad spectrum of scalp, hair and skin conditions.

FDA Approved and Clinically Tested

SOLV-XIM

Oily Scalp & Hair Treatment Shampoo

Treats & Controls Seborreah Dermatitus
 Treats & Controls Excessive Oily Scalp, Hair & Skin
 Reduces Inflammation & Irritated Scalp & Skin

- · Color Safe* Conditioning Formula
- · Weightless and Rinses 100% Clean

Drug Facts

Active ingredient

Purpose

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Uses • Helps control & prevent flaking & itching associated with seborrheic dermatitis

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SOLV X

salicylic acid shampoo

Prod	net	Info	uma	tion
Proa	11(.1	11110	rina	11011

Product Type HUMAN OTC DRUG Item Code (Source) NDC:59279-502

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	18 mg in 1 L

Inactive Ingredients			
Ingredient Name	Strength		
ACETIC MONOETHANOLAMIDE (UNII: A9 O 0 8 18 TWD)			
AMMO NIUM LAURYL SULFATE (UNII: Q7AO2R1M0B)			
ASCORBIC ACID (UNII: PQ6 CK8 PD0 R)			
BIOTIN (UNII: 6 S O 6 U 10 H 0 4)			

FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)	
COCO DIETHANOLAMIDE (UNII: 92005F972D)	
COCAMIDOPROPYL BETAINE (UNII: 50CF3O11KX)	
SARCO SINE (UNII: Z711V88R5F)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
INOSITOL (UNII: 4L6452S749)	
LINO LEIC ACID (UNII: 9KJL21T0QJ)	
LINO LENIC ACID (UNII: 0 RB V727H71)	
MENTHOL (UNII: L7T10EIP3A)	
PANTHENOL (UNII: WV9CM0O67Z)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
ALCOHOL (UNII: 3K9958V90M)	
JOJOBA OIL (UNII: 724GKU717M)	
SORBITOL (UNII: 506T60A25R)	
.ALPHATO CO PHERO L ACETATE, D- (UNII: A7E6112E4N)	
WHEAT GERM OIL (UNII: 14C97E680P)	
WATER (UNII: 059QF0KO0R)	
ZINC SULFATE (UNII: 89DS0H96TB)	

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:59279-502-33	1 L in 1 BOTTLE, PLASTIC			
2	NDC:59279-502-12	0.36 L in 1 BOTTLE, PLASTIC			
3	NDC:59279-502-06	0.18 L in 1 BOTTLE, PLASTIC			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part358H	0 1/0 1/19 9 4	

Labeler - Mediceutical Laboratories, LTD (136770067)

Registrant - Mediceutical Laboratories, LTD (136770067)

Establishment				
Name	Address	ID/FEI	Business Operations	
United 1 International Laboratories		807878116	manufacture(59279-502)	

Revised: 10/2012 Mediceutical Laboratories, LTD