X FOLATE- coal tar 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.

X-FOLATE

Active Ingredient

5% coal tar extract 0.75

Purpose

anti-dandruff, anti-psoriasis, anti-seborrheic dermatitis

Uses

Helps prevent and control itching and flaking associated with dandruff, psoriasis and 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 at least twice a week or as directed by a physician.

For maximum control, use every time you shampoo.

- 1. Wet hair massage a liberal amount of X-FolateTM into the scalp and leave on for 1-2 minutes.
- 2. Thorough rinse and repeat if desired.

Apply Therapeutic TM Scalp and Hair Treatment Rinse for 1-2 minutes, thoroughly rinse. For persistent dandruff and psoriasis use TheraRx TM as a pre-shampoo treatment.

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

Inactive Ingredients

Benzophenone-4, Caprylyl Glycol, Cocamidopropyl Betaine, Dicetyldimonium Chloride, Ethylhexyl Methoxycinnamate, Fragrance (Parfum), Hexylene Glycol, Magnesium Chloride, Menthol, Octocrylene, Olea Europea (Olive) Fruit Oil, Panthenol, Phenoxyethanol, Polyquaternium-7, Polyquaternium-10, Polysorbate 80, Salicylic Acid, Sodium Laureth Sulfate, Tocopheryl Acetate, Water (Aqua)

Package Label-Principal Display Panel

X-FOLATE TM

PERSISTENT DANDRUFF AND PSORIASIS TREATMENT SHAMPOO

MEDICEUTICALS®

Cruelty Free. Not tested on Animals

Sold exclusively through fine Salons, Spas and Medical Hair Restoration Clinics

Manufactured in the USA for:

Mediceutical Laboratories, LTD Fort Worth, Texas 76118

Customer Service: 1-800-433-2903

Medicuetical Europe B.V.

Kelvinstraat 61, 2723 RJ Zoetermeer, The Netherlands EU

Telphone: +31 79 3314029

NDC 5927950533 X-FOLATE TM 33.8 oz

NDC 5927950506 X-FOLATE TM 6 oz

NDC 5927950512 X-FOLATE $^{\mathrm{TM}}$ 12 oz

Front







SCALP THERAPIES

360 ml / 12 fl. oz. e

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

X-FOLATE M

Persistent Dandruff/Psoriasis Treatment Shampoo

- · Controls Flaky, Itchy Scalp
- · Treats Persistent Dandruff & Psoriasis
 - Safe for Color Treated Hair
 - Non-Drying, Conditioning Formula
 - · Rinses 100% Clean

Drug Facts

Active ingredient

Purpose

5% coal tar soluble extract 0.75...Anti-dandruff, Anti-psoriasis, Anti-seborrheic dermatitis

Uses • Helps prevent and control itching & flaking associated with dandruff, psoriasis and seborrheic dermatitis

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Directions

For best results use at least twice a week or as directed by a physician. For maximum control, use every time you shampoo.

- Wet hair, massage a liberal amount of X-Folate™ into the scalp and leave on for 1-2 minutes.

2. Throughly rinse and repeat if desired.

Apply Therapeutic™ Scalp & Hair Treatment Rinse for 1-2 minutes, thoroughly rinse. For persistent dandruff & psoriasis use TheraRx™ as a pre-shampoo treatment.

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

Inactive ingredients

Benzophenone-4, Caprylyl Glycol, Cocamidogropyl Betaine, Dicetyldimonium Chloride, Ethylnexyl Methoxycinnamate, Fragrance (Parfum), Hexylene Glycol, Magnesium Chloride, Menthol, Octocrylene, Olea Europea (Olive) Fruit Oil, Panthenol, Phenoxyethanol, Polyguaternium-7, Polyguaternium-10. Polysorbate 80, Salicylic Acid, Sodium Laureth Sulfate, Tocopheryl Acetate, Water (Aqua)

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X FOLATE

coal tar shampoo

Product Information

Product TypeHUMAN OTC DRUG LABELItem Code (Source)NDC:59279-505

Route of Administration TOPICAL DEA Schedule

Active Ingredient/Active Moiety

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Ingredient Name	Basis of Strength	Strength		
COAL TAR (COAL TAR)	COAL TAR	50 mg in 1 mL		

Inactive Ingredients	
Ingredient Name	Strength
SULISOBENZONE	
CAPRYLYL GLYCOL	
COCAMIDO PRO PYL BETAINE	
OCTINOXATE	
HEXYLENE GLYCOL	
MAGNESIUM CHLO RIDE	
MENTHO L	
OCTOCRYLENE	
OLIVE OIL	
PANTHENOL	
PHENOXYETHANOL	
POLYQUATERNIUM-7 (70/30 ACRYLAMIDE/DADMAC; 1600 KD)	
POLYSORBATE 80	
SALICYLIC ACID	
SO DIUM LAURETH SULFATE	
.ALPHATO COPHEROL ACETATE, D-	
WATER	

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:59279-505-33	1000 mL in 1 BOTTLE, PLASTIC			
2	NDC:59279-505-12	360 mL in 1 BOTTLE, PLASTIC			
3	NDC:59279-505-06	180 mL in 1 BOTTLE, PLASTIC			

OTC monograph final	part358H	0 1/0 1/19 9 3	
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Labeler - Mediceutical Laboratories, LTD (136770067)

Registrant - Mediceutical Laboratories, LTD (136770067)

Establishment				
Name	Address	ID/FEI	Business Operations	
United 1 International Laboratories		807878116	manufacture(59279-505)	

Revised: 10/2012 Mediceutical Laboratories, LTD