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-Folate™ into the scalp and leave on for 1-2 minutes.
2. Thorough rinse and repeat if desired.

Apply Therapeutic™ Scalp and Hair Treatment Rinse for 1-2 minutes, thoroughly rinse. For persistent dandruff and 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, Cocamidopropyl Betaine, Dicetyldimonium Chloride, Ethylhexyl Methoxycinnamate, Fragrance (Parfum), Hexylene Glycol, Magnesium Chloride, Menthol, Octocrylene, Olea Europea (Olive) Fruit Oil, Panthenol, Phenoxyethanol, Polyquaterniuim-7, Polyquaternium-10, Polysorbate 80, Salicylic Acid, Sodium Laureth Sulfate, Tocopheryl Acetate, Water (Aqua)

Package Label-Principal Display Panel

X-FOLATE™

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™ 33.8 oz

NDC 5927950506 X-FOLATE™ 6 oz

NDC 5927950512 X-FOLATE™ 12 oz
Front

X-FOLATE™

PERSISTENT DANDRUFF/PSORIASIS
TREATMENT SHAMPOO

EST. 1964

MEDICEUTICALS®

NDC 59279505 12

WWW.MEDICEUTICALLABS.COM

SCALP THERAPIES

360 ml / 12 fl. oz. ℮

Back

MEDICEUTICALS®

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™

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.

1. 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

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X FOLATE

coal tar shampoo

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:59279-505
Route of Administration	TOPICAL	**DEA Schedule**	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
COAL TAR (UNII: R533ESO2EC) (COAL TAR - UNII:R533ESO2EC)	COAL TAR	50 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
SULISOBENZONE (UNII: 1W6L629B4K)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
OCTINOXATE (UNII: 4Y5P7MUD51)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
MENTHOL (UNII: L7T10EIP3A)	
OCTOCRYLENE (UNII: 5A68WGF6WM)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
PANTHENOL (UNII: WV9CM0O67Z)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYQUATERNIUM-7 (70/30 ACRYLAMIDE/DADMAC; 1600 KD) (UNII: 0L414VCS5Y)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SALICYLIC ACID (UNII: O414PZ4LPZ)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	
WATER (UNII: 059QF0KO0R)	

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		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

OTC monograph final	part358H	01/01/1993	

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