

X-FOLATE PLUS- 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.

Mediceutical Laboratories - X-FOLATE PLUS (59279-516)

Active Ingredient

5% coal tar soluble extract

Purpose

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

Uses

Helps control and prevent flaking & itching associated with dandruff and seborrheic dermatitis.

Warnings

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

Keep this and all drugs out of the 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. Apply shampoo to wet hair, massage into hair and scalp, leave on for 2-3 minutes.
2. Thoroughly rinse and repeat if desired.
3. Apply Therapeutic scalp and hair treatment rinse for 2-3 minutes, thoroughly rinse.

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

Inactive Ingredients

Benzophenone-4, Caprylyl Glycol, Cocamidopropyl Betaine, Dicyldimonium 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).

X-FOLATE™*plus*

**PERSISTENT DANDRUFF/
PSORIASIS TREATMENT SHAMPOO**



MEDICEUTICALS®

SCALP THERAPIES

250 ML / 8.45 FL. OZ.

X-FOLATE™ plus

You have selected a professional dermatological product developed to help control a broad spectrum of scalp, hair and skin conditions.

- Controls dry, flaky & itchy scalp
- Treats persistent dandruff & psoriasis
 - Safe for color treated hair
- Non-drying, conditioning formula
- Weightless and rinses 100% clean

Drug Facts

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Sold through fine salons, spas & medical hair restoration clinics.

Manufactured in the USA for:

Mediceticals® USA
78 Henry Street
Secaucus 07094
New Jersey, USA

mediceticalsusa.com



X-FOLATE PLUS

coal tar shampoo

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59279-516
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
COAL TAR (UNII: R533ESO2EC) (COAL TAR - UNII:R533ESO2EC)	COAL TAR	5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
SULISOBENZONE (UNII: 1W6L629B4K)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
DICETYLDIMONIUM CHLORIDE (UNII: 6F4SX2007N)	
OCTINOXATE (UNII: 4Y5P7MUD51)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
MENTHOL (UNII: L7T10EIP3A)	
OCTOCRYLENE (UNII: 5A68WGF6VM)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
PANTHENOL (UNII: WW9CM0O67Z)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYQUATERNIUM-7 (70/30 ACRYLAMIDE/DADMAC; 1600 KD) (UNII: 0L414VCS5Y)	
POLYQUATERNIUM-10 (1000 MPAS AT 2%) (UNII: GMR4PEN8PK)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SALICYLIC ACID (UNII: O414PZ4LPZ)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59279-516-33	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/11/2021	
2	NDC:59279-516-08	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/11/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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Labeler - Mediceutical Laboratories, LTD (080520685)

Registrant - Mediceutical Laboratories, LTD (080520685)

Revised: 1/2022

Mediceutical Laboratories, LTD