X FOLATE- zinc pyrithione 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 - MEDICEUTICALS X-FOLATE (59279-506)

ACTIVE INGREDIENT

1% ZINC PYRITHIONE

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 poision 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

Water (Aqua), Sodium Olefin Sulfonate, Decyl Glucoside, Cocamide MEA,

Cocamidopropyl Hydroxysultaine, Zinc Pyrithione, Phenoxyethanol, Sodium Chloride, Climbazole, Polyquaternium-10 Panthenol, Allantoin, Fragrance (Parfum).



PERSISTENT DANDRUFF/ PSORIASIS TREATMENT SHAMPOO



SCALP THERAPIES

1 L / 33.8 FL. OZ.

X-FOLATE™

Persistent dandruff/psoriasis treatment shampoo

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

Active ingredient: 1% Zinc Pyrithione

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.

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Inactive ingredients: Water (Aqua), Sodium Olefin Sulfonate, Decyl Glucoside, Cocamide MEA, Cocamidopropyl Hydroxysultaine, Zinc Pyrithione, Phenoxyethanol, Sodium Chloride, Climbazole, Polyquaternium-10 Panthenol, Allantoin, Fragrance (Parfum). Mediceuticals® USA 78 Henry Street Secaucus 07094 New Jersey, USA

mediceuticalsusa.com



X-FOLATE™ PERSISTENT DANDRUFF/ **PSORIASIS TREATMENT SHAMPOO**



SCALP THERAPIES

250 ML / 8.45 FL. OZ.

X-FOLATE™

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

Active ingredient: 1% Zinc Pyrithione

Purpose: Anti-dandruff, anti-psoriasis & anti-seborrheic dermatitis.

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

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X FOLATE

zinc pyrithione shampoo

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:59279-506

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength

Inactive Ingredients

Ingredient Name		Strength
WATER (LINII: 0590F0KO0R)		

SODIUM C14-16 OLEFIN SULFONATE (UNII: O9W3D3YF5U)

DECYL GLUCOSIDE (UNII: Z17H97EA6Y)

COCO MONOETHANOLAMIDE (UNII: C80684146D)

COCAMIDOPROPYL HYDROXYSULTAINE (UNII: 62V75NI93W)

PHENOXYETHANOL (UNII: HIE492ZZ3T)
SODIUM CHLORIDE (UNII: 451W47IQ8X)

CLIMBAZOLE (UNII: 9N42CW7I54)

POLYQUATERNIUM-10 (1000 MPA.S AT 2%) (UNII: GMR4PEN8PK)

PANTHENOL (UNII: WW9CM0067Z)
ALLANTOIN (UNII: 344S277G0Z)

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Item Code Package Description Marketing Start Marketing End
Date Date

2 NDC:59279- 250 mL in 1 BOTTLE; Type 0: Not a Combination 04/29/2021 Product	1	NDC:59279- 506-33	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/29/2021	
	2			04/29/2021	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part358H	04/29/2021		

Labeler - Mediceutical Laboratories, LTD (080520685)

Revised: 1/2022 Mediceutical Laboratories, LTD