THERAPEUTIC - pyrithione zinc rinse 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.

THERAPEUTIC

Active ingredient

Pyrithione Zinc 0.5%

Purpose

anti-dandruff, anti-seborrheic, dermatitis

Uses

• Helps prevent recurrence of flaking and itching associated with dandruff 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 daily or until conditionis iunder control or as directed by a physician. For maximum control use every time you shampoo.

- 1. Cleanse with appropriate Mediceuticals® shampoo
- 2. Work ample amount of TherapeuticTM Scalp and Hair Treatment Rinse evenly through hair, gently massage onto the scalp, leave on 1-2 minutes
- 3. Thoroughly rinse

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

Inactive ingredients

Ascorbic Acid (Vitamin C), Behentrimonium Methosulfate, Blue 1 (CL 42090), Capryly Glycol, Cetearyl Alcohol, Cetyl Alcohol, Chamomilla Recutita (Matricaria) Extract, Ethylhexly Methoxycinnamate, Fragrance (Parfum), Gingko Biloba Root Extract, Guar Hydroxypropyltrimonium Chloride, Hamamelis Virginiana (Witch Hazel) Extract, Hexylene Glycol, Humulus Lupulus (Hops) Extract, Hydrastis Canadensis (Golden Seal) Extract, Menthol, Phenoxyethanol, Rosmarinius Officinalis (Rosemary) Extract, Tetrasodium EDTA, Wate (Aqua)

 $THERAPEUTIC^{TM}$

SCALP AND HAIR TREATMENT RINSE

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 Zoetermmer The Netherlands EU

Telephone: +31 79 3314029

NDC 5927951433 THERAPEUTIC $^{\text{TM}}$ 33.8 fl oz

NDC 5927951406 THERAPEUTIC TM 6 fl oz

NDC 5927951412 THERAPEUTIC TM 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

THERAPEUTIC™

Scalp & Hair Treatment Rinse

- · Re-acidifies Scalp & Hair
- · Helps control flaking & itching scalp
- · Promotes healthy scalp environment
- Excellent detangler & imparts shine
 Color safe & rinses 100% clean

Drug Facts

Active ingredient

Purpose

Pyrithione Zinc 0.5%......anti-dandruff, anti-seborrheic dermatitis

Uses • Helps prevent recurrence of flaking & itching associated with dandruff and seborrheic dermatitis Warnings

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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.

Cleanse with appropriate Mediceuticals® shampoo
 Work ample amount of Therapeutic™ Scalp and Hair Treatment Rinse evenly through the hair, gently massage onto the scalp, leave on 1-2 minutes

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

Inactive ingredients

Ascorbic Acid (Vitamin C), Behentrimonium Methosulfate, Blue 1 (Cl 42090), Caprylyl Glycol, Cetearyl Alcohol, Cetyl Alcohol, Chamomilla Recutita (Matricaria) Extract, Ethylhexyl Methoxycinnamate, Fragrance (Parfum), Gingko Biloba Root Extract, Guar Hydroxypropyltrimonium Chloride, Hamamelis Virginiana (Witch Hazel) Extract, Hexylene Glycol, Humulus Lupulus (Hops) Extract, Hydrastis Canadensis (Golden Seal) Extract, Menthol, Phenoxyethanol, Rosmarinus Officinalis (Rosemary) Extract, Tetrasodium EDTA, Water (Aqua)

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THERAPEUTIC

pyrithione zinc rinse

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Product Type HUMAN OTC DRUG Item Code (Source) NDC:59279-514

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PYRITHIONE ZINC (UNII: R953O2RHZ5) (PYRITHIONE ZINC - UNII:R953O2RHZ5)	PYRITHIONE ZINC	5 mg in 1 mL

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	Ingredient Name	Strength

ASCORBIC ACID (UNII: PQ6CK8PD0R)

FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
CAPRYLYL GLYCOL (UNII: 00 YIU5438 U)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
MATRICARIA RECUTITA (UNII: G0 R4UBI2ZZ)	
OCTINOXATE (UNII: 4Y5P7MUD51)	
GINKGO (UNII: 19FUJ2C58T)	
HAMAMELIS VIRGINIANA ROOT BARK/STEM BARK (UNII: T7S323PKJS)	
HEXYLENE GLYCOL (UNII: KEH0 A3F75J)	
HOPS (UNII: 01G73H6H83)	
GOLDENSEAL (UNII: ZW3Z11D0JV)	
MENTHOL (UNII: L7T10EIP3A)	
PHENO XYETHANO L (UNII: HIE49 2ZZ3T)	
ROSEMARY (UNII: IJ67X351P9)	
EDETATE SO DIUM (UNII: MP1J8420LU)	
WATER (UNII: 059QF0KO0R)	

P	Packaging							
#	Item Code	Package Description	Marketing Start Date	Marketing End Date				
1	NDC:59279-514-33	1000 mL in 1 BOTTLE, PLASTIC						
2	NDC:59279-514-12	360 mL in 1 BOTTLE, PLASTIC						
3	NDC:59279-514-06	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	0 1/0 1/20 0 7				

Labeler - Mediceutical Laboratories, LTD (136770067)

Registrant - Mediceutical Laboratories, LTD (136770067)

Establishment				
Name	Address	ID/FEI	Business Operations	
United 1 International Laboratories		807878116	manufacture (59279-514)	

Revised: 10/2012 Mediceutical Laboratories, LTD