THERAPEUTIC- zinc pyrithione 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.

Mediceutical Laboratories - THERAPEUTIC SCALP & HAIR TREATMENT RINSE (59279-515)

Active ingredient

Pyrithione Zinc 1%

Purpose

anti-dandruff, anti-seborrheic, dermatitis

Uses

HELPS CONTROL AND PREVENT FLAKING AND ITCHING ASSOCIATED WITH DANDRUFF AND SEBORRHEIC DERMATITUS.

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.

Avoid contact with eyes. If contact occurs, rinse eyes thoroughly with cool water.

Keep this and all drugs out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

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 Therapeutic TM 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 ${\tt @}$ scalp and hair treatment specifically tailored for your condition.

Inactive ingredients

WATER (AQUA), BEHENTRIMONIUM METHOSULFATE, CETEARYL ALCOHOL, CETYL ALCOHOL, PHENOXYETHANOL, GUAR HYDROXYPROPYLTRIMONIUM CHLORIDE, HUMULUS LUPULUS (HOPS) EXTRACT, ROSMARINUS OFFICINALIS (ROSEMARY) LEAF EXTRACT, HYDRASTIS CANADENSIS (GOLDENSEAL) EXTRACT, HAMAMELIS VIRGINIANA (WITCH hAZEL) LEAF EXTRACT, ASCORBIC ACID, ETHYLHEXYL METHOXYCINNAMATE, TETRASODIUM EDTA, MENTHOL, GINKGO BILOBA, FRAGRANCE (PARFUM), BLUE 1 (CI 42090).

THERAPEUTIC™

SCALP & HAIR TREATMENT RINSE



SCALP THERAPIES

250 ML / 8.45 FL. OZ.

THERAPEUTIC"

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

- · Re-acidifies scalp & hair
- Helps cantal flaking & itching scalp
- · Pramates healthy scalp environment
- · Excellent detangler & imparts shine
 - · Calarsafe & rinses 100% clean

Drug Fosts

Active Ingredient: 1% Zinc Pyrithiane

Purpose: Anti-dandruff & anti-sebarrheic dermatitis.

Uses: Helps control and prevent lioking & itching associated with dandruff and selsamheic dermatitis.

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

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Directions: For best results use doily or until condition is under control or as directed by a physician. For maximum control use every time you shampao.

- Cleanse with appropriate Mediceuticals shampoo
- Apply Therapeutic evenly through the hoir, gentle massage into the scalp. Leave on far 2-5 minutes.
- 3. Thoroughly rinse.

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

Ingredients: Water (Aqua), Behentrimonium Methasulfate, Cetearyl Alcahal, Cetyl Alcahal, Phenoxyethanal, Guar Hydraxypropyltrimonium Chloride, Humulus Lupulus (Hops) Extract, Rosmarinus Officinalis (Rosemary) Leaf Extract, Hydrastis Canadensis (Galdenseal) Extract, Hamannelis Virginiana (Witch Hazel) Leaf Extract, Ascorbic Acid, Ethylhexyl Methaxyainnamate, Tetrasadium EDTA, Menthal, Ginkga Bilaba, Fragrance (Parlum), Blue 1 (Cl. 42090).

Sold through fine solons, spoe & medical hair restoration clinics.

Montgloctured in the USA for: Mediceuticals® USA 78 Henry Street Secaucus 07094 New Jersey, USA

mediceuticaisusa.com



zinc pyrithione rinse

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:59279-515

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength

PYRITHIONE ZINC (UNII: R953O2RHZ5) (PYRITHIONE ZINC - UNII:R953O2RHZ5) PYRITHIONE ZINC 1 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
BEHENTRIMONIUM CHLORIDE (UNII: X7GNG3S47T)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
GUAR HYDROXYPROPYLTRIMONIUM CHLORIDE (1.7 SUBSTITUENTS PER SACCHARIDE) (UNII: B16G315W7A)	
HOPS (UNII: 01G73H6H83)	
ROSEMARY (UNII: IJ67X351P9)	
GOLDENSEAL (UNII: ZW3Z11D0JV)	
WITCH HAZEL (UNII: 101I4J0U34)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
OCTINOXATE (UNII: 4Y5P7MUD51)	
EDETATE SODIUM TETRAHYDRATE (UNII: L13NHD21X6)	

Packaging

MENTHOL (UNII: L7T10EIP3A)

GINKGO BILOBA WHOLE (UNII: 660486U6OI)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59279- 515-33	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/15/2020	
2	NDC:59279- 515-12	250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/15/2020	

Marketing Information	
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Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part358H	01/01/2007	
OTC monograph final	part358H	01/01/2007	

Labeler - Mediceutical Laboratories, LTD (080520685)

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