

THERA RX - triclosan solution
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.

THERA Rx

Active ingredient

Triclosan 0.3%

Purpose

Antibacterial

Uses

- Kills a broad spectrum of germs that may cause infections; first aid antiseptic to help prevent infection from minor cuts, scrapes, and burns. Promotes cleanliness and healing.

Warnings

For external use only. Do not apply over large areas of the body.

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 persistent dandruff and psoriasis conditions:

1. Apply Thera Rx™ directly to dry scalp
2. Gently work X-Folate™ Dandruff Treatment Shampoo onto the scalp, wrap the head within a hot towel, leave on 2-3 minutes, remove towel and thoroughly rinse. Reapply X-Folate™ working through the hair into a rich lather, leaving on for 1-2 minutes, thoroughly rinse.

Apply Therapeutic™ Scalp and Hair Treatment Rinse for 1-2 minutes, thoroughly rinse.

For Excessive oily scalp and seborrheic dermatitis conditions use Solv-X™ Oily Scalp Treatment Shampoo.

Other Uses: Oily skin astringent cleanser, acne, burns, insect bites, sun and wind burns, scratches, and minor wound treatment.

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

Inactive ingredients

Acetamide MEA, Ascorbic Acid (Vitamin C) Biotin, Blue1 (CI 42090), Camphor, Cocoyl Sarcosine, Ethylhexyl Methoxycinnamate, Fragrance (Parfum), Hydrolyzed Glycosaminoglycans, Hydrolyzed Keratin, Linoleic Acid, Linolenic Acid, Methanol, Panthenol, Polysorbate 80, Propylene Glycol, SD Alcohol 40-B, Simmondsia Chimensis (Jojoba) Seed Oil, Sodium Cocoyl Collagen Amino Acid,

Sorbitol, Tocopheryl Acetate, Triticum Vulgare (Wheat) Germ Oil, Water (Aqua), Wheat Germ Acid, Zinc Sulfate

Package Label-Principal Display Panel

THERA Rx™

ANTIBACTERIAL SCALP AND SKIN WASH

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 Zoetermeer, The Netherlands EU

Telephone: +31 79 3314029

NDC 5927953006 THERA Rx™ 6 fl oz

NDC 5927953012 THERA Rx™ 12 fl oz

Front

THERA Rx™

ANTI-BACTERIAL SCALP & SKIN WASH



EST. 1964

MEDICEUTICALS®

NDC 5927953012

MEDICEL

WWW.MEDICEUTICALLABS.COM

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

THERA_X[™]

Anti-bacterial Scalp and Skin Wash

- Kills Topical Fungus and Harmful Bacteria
- Reduces Redness, Itching and Inflammation
- Controls Excessive Oily Scalp and Skin
- All-Purpose First Aid Remedy

Drug Facts

| Active ingredient | Purpose |
|--------------------------|----------------|
| Triclosan 0.3%..... | Antibacterial |

Uses • Kills a broad spectrum of germs that may cause infections; first aid antiseptic to help prevent infection from minor cuts,

scrapes, and burns. Promotes cleanliness and healing.

Warnings

For external use only. Do not apply over large areas of the body.

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 persistent dandruff and psoriasis conditions:

1. Apply TheraRx™ directly to dry scalp
2. Gently work X-Folate™ Dandruff Treatment Shampoo onto the scalp, wrap the head within a hot towel, leave on 2-3 minutes, remove towel and thoroughly rinse. Reapply X-Folate™ working through the hair into a rich lather, leaving on for 1-2 minutes, thoroughly rinse.

Apply Therapeutic™ Scalp & Hair Treatment Rinse for 1-2 minutes, thoroughly rinse. For excessive oily scalp and seborrheic dermatitis conditions use Solv-X™ Oily Scalp Treatment Shampoo.

Other Uses: Oily skin astringent cleanser, acne, burns, insect bites, sun & wind burns, scratches, and minor wound treatment.

Consult your Salon professional for additional Medicetals® scalp and hair treatments specifically tailored for your condition.

Inactive ingredients

Acetamide MEA, Ascorbic Acid (Vitamin C), Biotin, Blue 1 (CI 42090), Camphor, Cocoyl Sarcosine, Ethylhexyl Methoxycinnamate, Fragrance (Parfum), Hydrolyzed Glycosaminoglycans, Hydrolyzed Keratin, Linoleic Acid, Lindelic Acid, Menthol, Panthenol, Polysorbate 80, Propylene Glycol, SD Alcohol 40-B, Simmondsia Chinensis (Jojoba) Seed Oil, Sodium Cocoyl Collagen Amino Acid, Sorbitol, Tocopheryl Acetate, Triticum Vulgare (Wheat) Germ Oil, Water (Aqua), Wheat Germ Acid, Zinc Sulfate

Cruelty Free. Not tested on Animals

**Sold exclusively through Fine Salons,
Spas & Medical Hair Restoration Clinics**

Manufactured in the USA for:

Medicetual Laboratories, LTD. Fort Worth, Texas 76118

Customer Service: 1-800-433-2903

Medicetual Europe B.V.

Kelvinstraat 61, 2723 RJ Zoetermeer

The Netherlands EU

Telephone: +31 79 3314029



THERA RX

triclosan solution

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:59279-530 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|--------------|
| TRICLOSAN (UNII: 4NM5039Y5X) (TRICLOSAN - UNII:4NM5039Y5X) | TRICLOSAN | 3 mg in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| ACETIC MONOETHANOLAMIDE (UNII: A9O0818TWD) | |
| ASCORBIC ACID (UNII: PQ6CK8PD0R) | |

| |
|--|
| BIOTIN (UNII: 6SO6U10H04) |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD) |
| CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) |
| SARCOSINE (UNII: Z711V88R5F) |
| OCTINOXATE (UNII: 4Y5P7MUD51) |
| LINOLEIC ACID (UNII: 9KJL21T0QJ) |
| LINOLENIC ACID (UNII: 0RBV727H71) |
| MENTHOL (UNII: L7T10EP3A) |
| PANTHENOL (UNII: WV9CM0O67Z) |
| POLYSORBATE 80 (UNII: 6OZP39ZG8H) |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) |
| ALCOHOL (UNII: 3K9958V90M) |
| JOJOBA OIL (UNII: 724GKU717M) |
| SORBITOL (UNII: 506T60A25R) |
| .ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N) |
| WHEAT GERM OIL (UNII: 14C97E680P) |
| WATER (UNII: 059QF0KO0R) |
| ZINC SULFATE (UNII: 89DS0H96TB) |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|-----------------------------|----------------------|--------------------|
| 1 | NDC:59279-530-12 | 360 mL in 1 BOTTLE, PLASTIC | | |
| 2 | NDC:59279-530-06 | 180 mL in 1 BOTTLE, PLASTIC | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333E | 01/01/1997 | |

Labeler - Mediceutical Laboratories, LTD (136770067)

Registrant - Mediceutical Laboratories, LTD (136770067)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------------------|---------|-----------|------------------------|
| United 1 International Laboratories | | 807878116 | manufacture(59279-530) |