

DR. CANUSO FOOT REPAIR SERUM- tolnaftate serum lotion
Renu Laboratories, Inc.

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.

Dr. Canuso foot repair serum TM

Tolnaftate 1%

Antifungal

When using this product

- Do not use on children under 2 years of age unless directed by a doctor
- Avoid contact with eyes
- **If irritation occurs**, discontinue use and consult a doctor
- **If swallowed**, get medical help or consult a poison control center immediately

KEEP OUT OF REACH OF CHILDREN

Other Information

Store at room temperature (59-86° F)

Inactive Ingredients

Acetylated Lanolin Alcohol, Acryloyldimethyl Taurate Copolymer, Benzoic Acid, Cetyl Acetate, Cyclopentasiloxane, Dehydroacetic Acid, Deionized Water, Dimethiconol, Ethoxydiglycol, Glycerin, Menthol, Menthyl Lactate, Olea Europaea (Olive Oil), PEG-12 Dimethicone, Phenoxyethanol, Phenyl Trimethicone, Polysorbate 60, Polysorbate 80, Propylene Glycol, Squalane, Talc.

Questions or Comments?

Visit www.DrCanuso.com

Directions

- Apply two pumps of serum onto each foot morning and night, paying special attention to rough cracked skin.
- For maintenance of smooth skin, massage two pumps of serum into each foot once daily.
- Supervise children in the use of this product.

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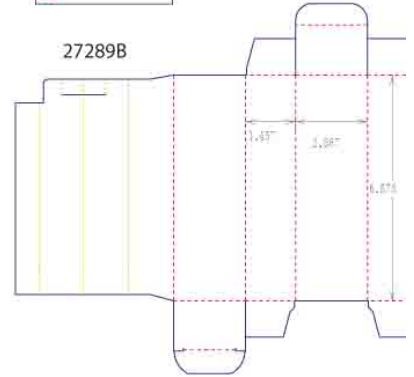
Proof Sign Off

Date _____ Art# 7916
 Approved
 Changes (Submit New PDF)
 Changes (Submit New Hard Proof)

Customer Signature Required to Proceed. Please read and check this proof carefully. The Manufacture accepts no responsibility for error, omissions or changes which are not clearly noted on this proof. Customers will be charged for any changes or additional proofs/plates that are not the direct results of errors made by The Manufacture.

Black
 Pantone 319
 Silver Foil

27289B



BOTTLE LABEL - Bottle resides in BOX

Dr. CANUSO™
SKINCARE



ULTRA HYDRATING

**foot
repair
serum™**

treats the causes of
dry skin & cracked heels

30ml/1oz

Drug Facts	<ul style="list-style-type: none"> For maintenance of smooth skin, massage two pumps of serum into each foot once daily. Supervise children in use of this product.
Active ingredient Purpose Tolnaftate 1%Antifungal	
Uses <ul style="list-style-type: none"> Relieves scaling and cracking Treats and prevents foot fungus (tinea pedis) 	Other information Store at room temperature (59-86°F)
Warnings When using this product <ul style="list-style-type: none"> Do not use on children under 2 years of age unless directed by a doctor Avoid contact with eyes If irritation occurs, discontinue use and consult a doctor If swallowed, get medical help or consult a poison control center immediately 	Inactive ingredients Acetylated Lanolin Alcohol, Acryoldimethyl Taurate Copolymer, Benzoic Acid, Cetyl Acetate, Cyclopentasiloxane, Dehydroacetic Acid, Deionized Water, Dimethiconol, Ethoxydiglycol, Glycerin, Hydroxyethylacrylate/Sodium, Menthol, Menthyl Lactate, Olea Europaea (Olive) Oil, PEG-12 Dimethicone, Phenoxyethanol, Phenyl Trimethicone, Polysorbate 60, Polysorbate 80, Propylene Glycol, Squalane, Talc
KEEP OUT OF REACH OF CHILDREN	
Directions <ul style="list-style-type: none"> Apply 2 pumps of serum onto each foot morning and night, paying special attention to rough cracked skin. 	<p>Questions or Comments? Visit www.DrCanuso.com Manufactured for: Dr. Canuso LLC, Atco, NJ 08004 © 2015 All Rights Reserved Dr. Canuso LLC</p>

DR. CANUSO FOOT REPAIR SERUM

tolnaftate serum lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76348-409
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TOLNAFTATE (UNII: 06KB629TKV) (TOLNAFTATE - UNII:06KB629TKV)	TOLNAFTATE	0.3 g in 28 g

Inactive Ingredients

Ingredient Name	Strength
OLIVE OIL (UNII: 6UYK2W1W1E)	
DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A1I8X02B)	
MENTHOL (UNII: L7T10EIP3A)	

DEHYDROACETIC ACID (UNII: 2KAG279R6R)
TALC (UNII: 7SEV7J4R1U)
POLYSORBATE 80 (UNII: 6OZP39ZG8H)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
PEG-12 DIMETHICONE (300 CST) (UNII: ZEL54N6W95)
GLYCERIN (UNII: PDC6A3C0OX)
CETYL ACETATE (UNII: 4Q43814HXS)
ACETYLATED LANOLIN ALCOHOLS (UNII: SNN716810P)
WATER (UNII: 059QF0KO0R)
MENTHYL LACTATE, (-)- (UNII: 2BF9E65L7I)
DIMETHICONE (UNII: 92RU3N3Y1O)
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)
2-HYDROXYETHYL ACRYLATE (UNII: 25GT92NY0C)
SODIUM ACRYLOYLDIMETHYLTAURATE (UNII: 2T9Q6EKI0G)
SQUALANE (UNII: GW89575KF9)
POLYSORBATE 60 (UNII: CAL22UVI4M)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
BENZOIC ACID (UNII: 8SKN0B0MIM)

Product Characteristics

Color	white (Serum)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76348-409-02	1 in 1 BOX	08/20/2015	
1		28 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	08/20/2015	

Labeler - Renu Laboratories, Inc. (945739449)

Establishment

Name	Address	ID/FEI	Business Operations
Renu Laboratories, Inc.		945739449	manufacture(76348-409)

