## FORMULA 7 - THE SOLUTION- tolnaftate solution The Tetra Corporation

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#### Formula 7 The SOLUTION

#### **Uses:**

**Antifungal** 

#### **Indication**

For effective treatment of most athlete's foot (tinea pedis) and ringworm (tinea corporis). Relieves:

- Itching
- Scaling
- Cracking
- Redness
- Soreness
- Burning
- Irritation

Prevents the recurrence of most athlete's foot with daily use.

## **Active ingredient**

Tolnaftate 1%

### Stop use and ask a doctor if:

- When using for treatment of athlete's foot or ringworm: If irritation occurs or if there is no improvement within 4 weeks, discontinue use and consult a doctor.
- When using for prevention of athlete's foot: If irritation occurs, discontinue use and consult a doctor.

#### DO NOT USE SECTION

**Do not use**on children under 2 years of age unles as directed by a doctor.

#### PREGNANCY OR BREAST FEEDING

If pregnant or breast-feeding ask a health professional before use.

#### Questions or comments?

1-800-826-0479 9:00 AM to 5:30 PM EST.

### **Inactive Ingredients**

Inactive Ingredients: Water (aqua),C12-15 Alkyl Benzoate, SimmondsiaChinensis (Jojoba) Oil, Glycerin,Oleth-10, Oleth-5, Oleth-3 Phosphate,PEG-20 Hydrogenated Lanolin,Butylene Glycol, Urea, Ethoxydiglycol,N-Acetyl-L-Cysteine, TocopherolAcetate (Vitamin E), Melaleuca

Alternifolia (Tea Tree) Oil, DisodiumEDTA, Ethylhexylglycerin, CaprylylGlycol, Phenoxyethanol, Aminomethylpropanediol, Sodium Chloride.

#### **Directions:**

For treatment of athlete's foot, and ring worm.

- Clean the affected area and dry thoroughly. Apply a thin layer of the product over the affected area twice daily (morning and night) or as directed by a doctor.
- Supervise children in the use of this product.
- For athlete's foot: Pay special attention to spaces between the toes; wear well-fitting, ventilated shoes, and change shoes and socks at least once daily.
- For athlete's foot and ringworm, use daily for 4 weeks.
- If condition persists longer, consult a doctor. This product is not effective on the scalp or nails.

To prevent athlete's foot:

- Wash the feet and dry thoroughly.
- Apply a thin layer of the product to the feet once or twice daily (morningand/or night).
- Supervise children in the use of this product.
- Pay special attention to spaces between the toes; wear well-fitting, ventilated shoes, and change shoes and socks at least once daily

## Storage

Store above 12°C (55°F).

## **Warnings**

For external use only.

When using this product avoid contact with eyes.

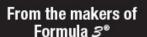
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

NDC #49406-007-15

MICROEMULSION



NANOPARTICLE PENETRATION



DISPENSED ONLY BY PHYSICIANS

NET WT 15g (1/2 oz.)

#### To Treat Fungal Infection:

Use Formula 7° twice daily, or as directed by your doctor, to effectively treat your fungal skin infection and improve the appearance of your nails. Once treated, continue to use Formula 7º once daily to prevent tinea pedis from reoccurring.

#### First Time Use -Loading the brush for the first time:

Place the dry brush on the infected area and squeeze the tube gently while moving the brush. As soon as the brush stroke reveals product is flowing, stop applying pressure and use the loaded brush to cover the entire infected area with medicine. Apply gende pressure again when brush is no longer delivering product.



#### Everyday Application:

Remove the cover and, without squeezing the tube, use the loaded brush to cover the entire infected area with medicine. Apply gentle pressure when brush is no longer delivering product.

# ormu THE SOLUTION

Tolnaftate 1% Antifungal Solution

#### Drug Facts

Active ingredient Tolnaftate 1%.....

Purpose

Uses: For effective treatment of most athlete's foot (tinea pedis) and ringworm (tinea corporis)

Relieves: \* Itching \* Scaling \* Cracking Redness • Soreness • Burning • Irritation Prevents the recurrence of most athlete's foot with

#### Warnings:

For external use only.

When using this product avoid contact with eyes.

- Stop use and ask a doctor if:

   When using for treatment of athlete's foot or ringworm: If irritation occurs or if there is no improvement within 4 weeks, discontinue use and consult a doctor.

  • When using for prevention of athlete's foot: If
- irritation occurs, discontinue use and consult

Do not use on children under 2 years of age unless

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away

If pregnant or breast-feeding ask a health professional before use.

1-800-826-0479 9:00 AM to 5:30 PM EST.





For more information, visit our website at: www.TheTetraCorp.com

#### Drug Facts (continued)

Directions:

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- on the scalp or nails.

To prevent athlete's foot:

- Wash the feet and dry thoroughly.
- Apply a thin layer of the product to the feet once or twice daily (morning and/or night).
- Supervise children in the use of this product.
- Pay special attention to spaces between the toes; wear well-fitting, ventilated shoes, and change shoes and socks at least once daily.

Store above 12°C (55°F).

Inactive Ingredients: Water (equa), C12-15 Alkyl Benzoate, Simmondsix Chinensis (Jojoba) Oli, Glycarin, Oleth-10, Oleth-5, Oleth-3 Phosphate, PEG-20 Hydrogenated Lanolin, Butylene Glycol, Urea, Ethoxydighycol, Burgleria dryco, orea, canoxyargyo N-Acstyl-L-Cysteine, Tocopherol Acstate (htamin E), Melaleuca Atternifolia (fea Tree) Oil, Disodium EDTA, Ethylhesylghycerin, Caprylyl Glycol, Phenoxyethanol, Aminomet ylpropanediol, Sodium Chloride.



Manufactured for THE TETRA CORPORATION Eaton Rapids, MI 48827

## **FORMULA 7 - THE SOLUTION**

tolnaftate solution

#### **Product Information**

HUMAN OTC DRUG NDC:49406-007 **Product Type** Item Code (Source)

**Route of Administration TOPICAL** 

## **Active Ingredient/Active Moiety**

Ш	Ingredient Name	<b>Basis of Strength</b>	Strength
-	TOLNAFTATE (UNII: 06KB629TKV) (TOLNAFTATE - UNII:06KB629TKV)	TOLNAFTATE	1 a in 100 a

#### **Inactive Ingredients**

**Ingredient Name** 

Strength

WATER (UNII: 059QF0KO0R)	
JOJOBA OIL (UNII: 724GKU717M)	
GLYCERIN (UNII: PDC6A3C0OX)	
<b>OLETH-10</b> (UNII: JD797EF70J)	
<b>OLETH-5</b> (UNII: 1GH33785AY)	
OLETH-3 PHOSPHATE (UNII: 8Q0Z18J1VL)	
PEG-20 HYDROGENATED LANOLIN (UNII: 5PP3KJ4T6S)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
UREA (UNII: 8W8T17847W)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TEA TREE OIL (UNII: VIF565UC2G)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ACETYLCYSTEINE (UNII: WYQ7N0BPYC)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	

l	P	Packaging						
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
	1	NDC:49406-007- 15	15 g in 1 PACKAGE; Type 0: Not a Combination Product	06/13/2018				

Marketing In	rketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M005	06/13/2018		

## **Labeler -** The Tetra Corporation (829958409)

## Registrant - The Tetra Corporation (829958409)

Revised: 10/2023 The Tetra Corporation