

**FORMULA 7 THEGEL- tolnaftate gel**  
**The Tetra Corporation**

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**Formula 7 THE GEL**

**Uses:**

Antifungal

For effective treatment of most athlete's foot and ringworm.

Relieves:

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

Prevents the recurrence of most athlete's foot (dermatophytosis) 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 the 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 unless 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, Simmondsia Chinensis (Jojoba) Oil, Glycerin, Oleth-10, Oleth-5, Oleth-3 Phosphate, PEG-20 Hydrogenated Lanolin, Butylene Glycol, Urea, Ethoxydiglycol, N-Acetyl-L-Cysteine, Tocopherol Acetate (Vitamin E), Melaleuca Alternifolia (Tea Tree) Oil, Disodium EDTA, Ethylhexylglycerin, Caprylyl Glycol, Phenoxyethanol, Aminomethylpropanediol, Sodium Chloride.

## **Directions:**

For treatment of athlete's foot and ringworm:

- 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 (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.

## **Other information**

Store at room temperature, 25°C (77°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.

## **Product Label**



**Also dispensed by physicians:**

- Formula 3<sup>®</sup>
- FunglFoam<sup>®</sup>
- CleanSweep<sup>®</sup>
- Kamea 20<sup>®</sup>
- Kamea G<sup>®</sup>
- CoLig-10™

**Drug Facts (continued)**  
**Directions:** For treatment of athlete's foot & ringworm:  
 • 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.  
 ◀ continued

**Drug Facts (continued)**  
**Warnings: (continued)**  
**Stop use and ask a doctor if:**  
 • When using for 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 the prevention of athlete's foot: If irritation occurs, discontinue use and consult a doctor.  
**If pregnant or breast-feeding** ask a health professional before use.  
**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.  
 ◀ continued

**Drug Facts**  
**Active ingredient Purpose**  
 Tolnaftate 1% .....Antifungal  
**Uses:** For effective treatment of most athlete's foot and ringworm.  
 Relieves: • Itching • Scaling  
 • Cracking • Redness • Soreness  
 • Burning • Irritation. Prevents the recurrence of most athlete's foot (dermatophytosis) with daily use.  
**Warnings: For external use only.**  
 Do not use on children under 2 years of age unless directed by a doctor.  
 When using this product avoid contact with the eyes.  
 ◀ continued

NDC #49406-008-30  
**Formula 7 Rapid MicroGel**  
 Tolnaftate 1% Antifungal Gel  
**NANOPARTICLE PENETRATION**  
 DISPENSED ONLY BY PHYSICIANS  
 Net Wt. 1 oz. (28g)

**Drug Facts (continued)**  
**Other information:** Store at room temperature, 25° (77°F).  
**Inactive ingredients:** Water (aqueous), C12-15 Alkyl Benzoate, Glycerin, Oleth-10, Oleth-5, Oleth-3, Phosphate, Simmondsia Chinensis (Jojoba) Oil, Butylene Glycol, Urea, Ethoxydiglycol, N-Acetyl-L-Cysteine, Tocopherol Acetate (Vitamin E), Melaleuca Alternifolia (Tea Tree) Oil, Ethylhexylglycerin, Caprylyl Glycol, Phenoxethanol, Aminomethylpropanediol.  
 Questions or comments? 1-800-826-0479 9:00 AM to 5:30 PM EST. TheTetraCorp.com

**Drug Facts (continued)**  
**Directions: (continued)**  
 • 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 (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.  
 ◀ continued

## FORMULA 7 THEGEL

tolnaftate gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:49406-008
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TOLNAFTATE (UNII: 06KB629TKV) (TOLNAFTATE - UNII:06KB629TKV)	TOLNAFTATE	1 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
JOJOBA OIL (UNII: 724GKU717M)	
GLYCERIN (UNII: PDC6A3C0OX)	
OLETH-10 (UNII: JD797EF70J)	

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

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49406-008-30	15 g in 1 PACKAGE; Type 0: Not a Combination Product	06/13/2018	
2	NDC:49406-008-28	28 g in 1 JAR; Type 0: Not a Combination Product	01/28/2020	

### Marketing 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)