

FORMULA 7 - THE SOLUTION- tolnaftate solution
The Tetra Corporation

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 unless 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, 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 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 (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.

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.

Product label

Formula
THE SOLUTION
Tolnaftate 1% Antifungal Solution

MICROEMULSION

**NANOPARTICLE
PENETRATION**

Patent 10959975

NDC #49406-007-15
NET WT 15g (1/2 oz.)

Active ingredient	Purpose
Tolnaftate 1%	Antifungal
Uses ■ proven clinically effective in the treatment of most athlete's foot (tinea pedis) and ringworm (tinea corporis) ■ helps prevent most athlete's foot with daily use ■ for effective relief of itching, burning and cracking	
Warnings For external use only	
When using this product avoid contact with eyes.	
Stop use and ask a doctor if ■ irritation occurs ■ there is no improvement within 4 weeks	
Do not use on children under 2 years of age except under the advice and supervision of a doctor.	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
Directions ■ wash affected area and dry thoroughly ■ apply a thin layer over affected area twice daily (morning and night) ■ 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 ■ use daily or 4 weeks; if condition persists longer, ask a doctor ■ to prevent athlete's foot, apply once or twice daily (morning and/or night) ■ this product is not effective on the scalp or nails	
Store above 12°C (55°F). Questions? 800-826-0479 Formula 7® is a registered Trademark of Tetra. ©2018 The Tetra Corporation. Dist By: The Tetra Corporation, Eaton Rapids, MI 48827 Made in a USA, FDA Registered Laboratory. Batch Code and Exp. Date – See Crimp. www.TheTetraCorp.com	

Formula
THE SOLUTION
Tolnaftate 1% Antifungal Solution
Professional Size
NET WT 15g (1/2 oz.)

Ask your doctor
about
Clean Sweep
ANTIMICROBIAL SHOE SHELDER

NDC #49406-007-15



Drug Facts

Active Ingredient Tolnaftate 1%
Purpose Antifungal

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 daily use.

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 and consult a doctor.

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

Do not use on children under 2 years of age unless directed by a doctor.

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.

Questions or comments?
1-800-826-0470 9:00 AM to 5:30 PM EST.



Made in a USA, FDA
Registered Laboratory



Visit our website at
TheTetraCorp.com

Drug Facts (continued)

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 socks, 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 socks at least once daily.

Other information:

Store above 12°C (55°F).

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, Ethoxdiglycol, N-Acetyl-L-Cysteine, Tocopherol Acetate (Vitamin E), Melaleuca Alternifolia (Tea Tree) Oil, Disodium EDTA, Ethylhexylglycerin, Caprylyl Glycol, Phenoxethanol, Aminomethylpropanediol, Zinc Citrate.



Manufactured for
THE TETRA CORPORATION
Eaton Rapids, MI 48827

MICROEMULSION



NANOPARTICLE
PENETRATION

U.S. PATENT #10959975

From the makers of
Formula 3

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 7[®] 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 gentle 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.

FORMULA 7 - THE SOLUTION

tolnaftate solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49406-007
Route of Administration	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)	
OLETH-5 (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)	
.ALPHA.-TOCOPHEROL 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)	

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 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)