

FORMULA 3- tolnaftate solution
The Tetra Corporation

FORMULA 3

Active ingredient:

Tolnaftate 1%

Purpose

Antifungal

Uses:

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

Relieves:

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

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 eyes.

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 breastfeeding 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.

Directions**For treatment of athlete's foot and ringworm**

- Clean the affected area and dry thoroughly. Apply a thin layer of the product over 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 scalp or nail.

To prevent athlete's foot:

- Clean 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.

Inactive ingredients

Apricot Kernel Oil, Rice Bran Oil, Sesame Seed Oil, Safflower Oil, simmondsia chinensis, Vitamin E Acetate, Methyl Paraben, Propyl Paraben and Butyl Paraben.

Product label

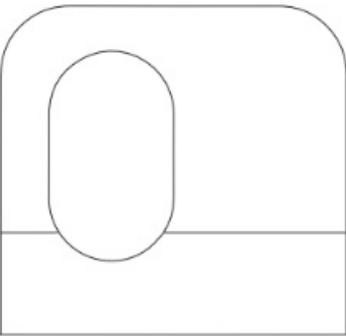
Cut along folds
for instructions.



See Instructions Below

Application Instructions

Apply twice daily over
affected area with brush or
as directed by your doctor.
If you have any questions,
contact your doctor before
beginning use of this
product. Continue
treatment until your next
doctor's appointment. Only
use this product under the
direction of a physician.



Ask your doctor about
FungiFoam
ANTIFUNGAL

The Treatment
Formula 3[®] ANTIFUNGAL
Professional
Tolnaftate 1% Antifungal Solution
Professional Size: 1/2 oz (15ml)

Ask your doctor about
CleanSweep
ANTIFUNGAL SHOE POWDER

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.
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

Also dispensed by physicians:

Formula 7[®]
FungiFoam[®]
CleanSweep[®]
Kamea 20[®]
Kamea G[®]
CoLig-10™



Made in a USA, FDA Registered Laboratory

Questions or comments?
1-800-826-0479
Monday through Friday
9:00 AM to 5:30 PM Eastern Time



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Manufactured for
THE TETRA CORPORATION
Easton Rapids, MI 48827
www.Formula3.com

NDC #49406-003-15

The Treatment
Formula 3[®] ANTIFUNGAL
Professional

Formula 3[®] Brand Antifungal
Tolnaftate 1% Antifungal Solution

Dispensed Only by Physicians

Professional Size: 1/2 oz (15ml)

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 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:

- Clean 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.

Inactive Ingredients:
Apricot Kernel Oil, Rice Bran Oil, Sesame Seed Oil, Safflower Oil, Simmondsia Chinensis, Vitamin E Acetate, Methyl Paraben, Propyl Paraben, and Butyl Paraben.

tolnaftate solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49406-003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TOLNAFTATE (UNII: 06KB629TKV) (TOLNAFTATE - UNII:06KB629TKV)	TOLNAFTATE	10 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
APRICOT KERNEL OIL (UNII: 54JB35T06A)	
RICE BRAN OIL (UNII: LZ06K1506A)	
SESAME OIL (UNII: QX10HYY4QV)	
SAFFLOWER OIL (UNII: 65UEH262IS)	
JOJOBA OIL (UNII: 724GKU717M)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
BUTYLPARABEN (UNII: 3QPI1U3FV8)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49406-003-15	1 in 1 BOX	10/30/2012	
1		15 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M005	10/30/2012	

Labeler - The Tetra Corporation (829958409)

Registrant - The Tetra Corporation (829958409)