

FORMULA 3- tolnaftate solution
Canadian Custom Packaging Company

FORMULA 3

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, Jojoba Oil, Vitamin E Acetate, Methyl Paraben, Propyl Paraben and Butyl Paraben.

FORMULA 3 BRAND Antifungal Tolnaftate 1% Antifungal Solution 15ml (49406-003-15)

Representative Labeling

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

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■ 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 ►

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.

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



Made in a USA, FDA Registered Laboratory

Questions or comments?

1-800-826-0479

Monday through Friday

9:00 AM to 6:00 PM Eastern Time.



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Manufactured for
THE TETRA CORPORATION
Eaton Rapids, MI 48827

www.Formula3.com

NDC #49406-003-15

The Treatment

Formula 3[®]

Professional

ANTIFUNGAL

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

APPROVED



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 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, Jojoba Oil, Vitamin E Acetate, Methyl Paraben, Propyl Paraben and Butyl Paraben.

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.

FORMULA 3[®]
TOLNAFTATE 1%
ANTIFUNGAL SOLUTION

Active ingredient: Tolnaftate 1%

Uses: Treats most athlete's foot and ringworm. 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 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.

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.

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 scalp or nail infections.

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, jojoba oil, Vitamin E Acetate, Methyl, Propyl and Butyl Parabens.

Net Contents 1/2 oz. (15ml.)

BATCH:

EXP. DATE:

Manufactured for
THE TETRA CORPORATION
Eaton Rapids, MI 48827
800-826-0479

FORMULA 3

tolnaftate solution

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:54291-036

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: LZO6K1506A)	
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:54291-036-01	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 - Canadian Custom Packaging Company (207062514)

Registrant - Canadian Custom Packaging Company (207062514)

Establishment

Name	Address	ID/FEI	Business Operations
Canadian Custom Packaging Company		207062514	manufacture(54291-036)