FORMULA 3- tolnaftate solution The Tetra Corporation

FORMULA 3

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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 useon 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 breastfeedingask 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:

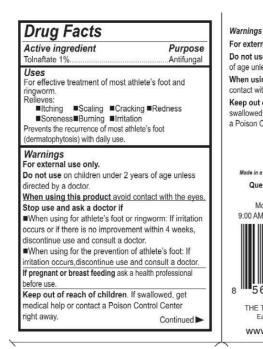
- Clean the feet and dry thoroughly.
- Apply a thin layer of the product to the feet once or twice daily (morning and/or night)
- Supervise children in the use of this product.
- Pay special attention to spaces between the toes; wear well fitting, ventilated shoes, and change shoes and socks at least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



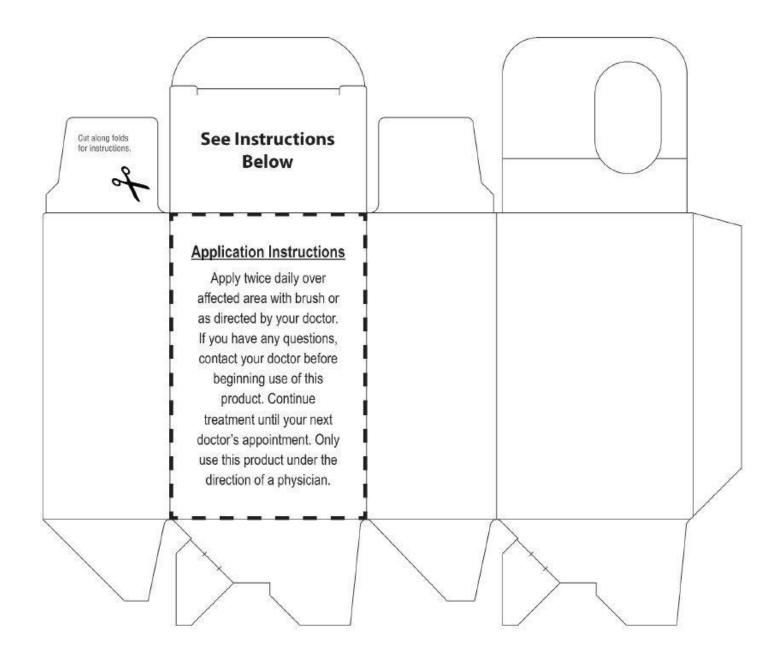


Drug Facts (continued) Directions For treatment of athlete's foot and ringworm Clean the affected area and dry thoroughly. Apply a thin layer of the product over affected area twice daily (morning and night) or as directed by a doctor. Supervise children in the use of this produce For athlete's foot: Pay special attention to spaces between the toes; wear well fitting, entilated 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

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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° 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:49406-003

	istration	TOPICAL		
Active Ingredi	ient/Active	Moiety		
Ingredient Name		Basis of Stren	igth Strength	
TOLNAFTATE (UNII	: 06KB629TKV)	(TOLNAFTATE - UNII:06KB629TK\	/) TOLNAFTATE	10 mg in 1 mL
Inactive Ingre	dients			
	Strength			
APRICOT KERNEL	OIL (UNII: 54JB3	35T06A)		
RICE BRAN OIL (UI	NII: LZO6K1506A	A)		
SESAME OIL (UNII:	QX10HYY4QV)			
SAFFLOWER OIL (UNII: 65UEH262	IS)		
JOJOBA OIL (UNII: 7	724GKU717M)			
ALPHATOCOPHE	ROL ACETATE	(UNII: 9E8X80D2L0)		
METHYLPARABEN	(UNII: A2I8C7HI	ЭТ)		
PROPYLPARABEN	(UNII: Z8IX2SC1	OH)		
PROPYLPARABEN BUTYLPARABEN (L				
BUTYLPARABEN (U				
BUTYLPARABEN (U				
BUTYLPARABEN (U Packaging	JNII: 3QPI1U3FV		Marketing Start Date	Marketing End Date
BUTYLPARABEN (U Packaging # Item Code	JNII: 3QPI1U3FV Pa	8)	-	-
BUTYLPARABEN (U Packaging # Item Code 1 NDC:49406-003- 15	JNII: 3QPI1U3FV Pa 1 in 1 BOX	8)	Date 10/30/2012	-
BUTYLPARABEN (U Packaging # Item Code 1 NDC:49406-003- 15	JNII: 3QPI1U3FV Pac 1 in 1 BOX 15 mL in 1 BO ⁻	⁸⁾ ckage Description	Date 10/30/2012	-
BUTYLPARABEN (U Packaging # Item Code 1 NDC:49406-003- 15 1	JNII: 3QPI1U3FV Pac 1 in 1 BOX 15 mL in 1 BO ⁻ Product	8) ckage Description ITLE; Type 0: Not a Combination	Date 10/30/2012	-
BUTYLPARABEN (U Packaging # Item Code	JNII: 3QPI1U3FV Pac 1 in 1 BOX 15 mL in 1 BO ⁻ Product Informat	8) ckage Description ITLE; Type 0: Not a Combination	Date 10/30/2012	-

Labeler - The Tetra Corporation (829958409)

Registrant - The Tetra Corporation (829958409)

Revised: 10/2023

The Tetra Corporation