

TOLNAFI-AL- tolnaftate liquid
True Marker Pharmaceuticals, Inc.

Drug Facts

Active Ingredient (s)

Tolnaftate 1%

Purpose

Antifungal

Uses □

- Proven clinically effective in the treatment of most fungal infections including related/associated to tinea pedis (athlete's foot), tinea cruris (jock itch) and tinea corporis (ringworm)
- For effective relief of itching, scaling, cracking, burning, redness, soreness, irritation, discomfort associated to fungal infections
- Prevents most tinea pedis (athlete's foot) 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**
 - for athlete's foot and ringworm - if irritation occurs or there is no improvement within 4 weeks
 - for prevention of athlete's foot - if irritation occurs, discontinue use and consult a doctor
 - for athlete's foot and ringworm - if irritation occurs or there is no improvement within 4 weeks
 - for prevention of athlete's foot - if irritation occurs, discontinue use and consult a doctor

Inactive ingredients

If swallowed, get medical help or contact a Poison Control Center right away

Directions

- clean the affected area and dry thoroughly
- apply a thin layer of the product over affected area twice daily (morning and night) paying special attention to the edges of the nail, cuticles and skin around the nails 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.

Other information

- Store at 15 - 30°C (59 - 86°F)
- avoid excessive heat
- do not use if package is damaged

Inactive Ingredients

Helianthus annuus flowering top, Vitis Vinifera Fruit Oil, Peppermint, Alpha-Tocopherol Acetate, Butylated Hydroxytoluene.

Product label

The image shows a yellow product label for Tolnafi-AL. The front panel on the left includes the NDC number 83592-480-01, '2 Pack', the product name 'Tolnafi-AL', 'Tolnaftate 1% Liquid', 'Antifungal', and the 'true marker' logo. The net content is 2 fl oz/60 ml. The label is divided into three columns of text:

Column 1 (Left)	Column 2 (Middle)	Column 3 (Right)	
<p>NDC 83592-480-01</p> <p>2 Pack</p> <p>Tolnafi-AL</p> <p>Tolnaftate 1% Liquid</p> <p>Antifungal</p> <p>true marker</p> <p>Net Content 2 fl oz/60 ml</p> <p>*Contains 2 Bottles of 1 fl oz/30 ml</p>	<p>Drug Facts</p> <p>Active ingredient Purpose Tolnaftate 1%...Topical Antifungal</p> <p>Uses</p> <ul style="list-style-type: none">■ Proven clinically effective in the treatment of most fungal infections including related / associated to tinea pedis (athlete's foot), tinea cruris (jock itch) and tinea corporis (ringworm).■ For effective relief of itching, scaling, cracking, burning, redness, soreness, irritation, discomfort associated to fungal infections■ Prevents most tinea pedis (athlete's foot) with daily use. <p>Warnings</p> <p>For external use only</p> <p>Do not use ■ on children under 2 years of age unless directed by a doctor</p> <p>When using this product</p> <ul style="list-style-type: none">■ Avoid contact with the eyes. <p>Stop use and ask a doctor</p> <ul style="list-style-type: none">■ If irritation occurs or if there is no improvement within 4 weeks, discontinue use and consult a doctor (within 2 weeks for jock itch).	<p>Drug Facts (continued)</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p> <p>If pregnant or breast-feeding, ask a health professional before use</p> <p>Directions</p> <ul style="list-style-type: none">■ 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.■ Pay special attention to spaces between the toes; wear well-fitting, ventilated shoes, and change shoes and socks at least once daily.■ 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.	<p>Drug Facts (continued)</p> <p>Other information</p> <ul style="list-style-type: none">■ Protect the product in this container from excessive heat and direct sun. <p>Inactive ingredients</p> <p>Helianthus Annuus (Sunflower) Oil, Vitis Vinifera (Grape) Seed Oil, Mentha Piperita (Peppermint) Oil, Tocopheryl Acetate (Vitamin E), BHT (Butylated hydroxytoluene).</p> <p>Questions? 602-887-9879</p> <p>Manufactured For: True Marker Pharmaceuticals, Inc. Phoenix, AZ 85040</p> <p>EXP DATE:</p>

NDC 83592-480-30



Tolnafi-AL

Tolnaftate 1% Liquid

Antifungal



EXP. DATE:

Net Wt. 1 fl oz / 30 mL

true marker

Drug Facts

Active ingredients	Purposes
Tolnaftate 1%	Antifungal
Uses	
<ul style="list-style-type: none"> for the treatment of most athlete's foot (tinea pedis) and ringworm (tinea corporis). relieves itching, burning, cracking, scaling and discomfort which accompany these conditions. for the prevention of most Athlete's foot with daily use. eliminates fungus on fingers, toes and around the nails. eliminates and helps stop the spread of fungal infections on cuticles around nail edges and under the nail tips where reachable with applicator brush. 	
Warnings	
For external use only	
Do not use on children under 2 years of age	
When using this product do not get into eyes	
Stop use and ask a doctor	
<ul style="list-style-type: none"> for athlete's foot and ringworm - if irritation occurs or there is no improvement within 4 weeks for prevention of athlete's foot - if irritation occurs, discontinue use and consult a doctor for athlete's foot and ringworm - if irritation occurs or there is no improvement within 4 weeks for prevention of athlete's foot - if irritation occurs, discontinue use and consult a doctor 	
Directions	
<ul style="list-style-type: none"> clean the affected area and dry thoroughly apply a thin layer of the product over affected area twice daily (morning and night) paying special attention to the edges of the nail, cuticles and skin around the nails 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. 	
Other information	
<ul style="list-style-type: none"> Store at 15 - 30°C (59 - 86°F) avoid excessive heat do not use if package is damaged 	
Inactive ingredients	
Helianthus annuus flowering top, Vitis Vinifera Fruit Oil, Peppermint, Alpha-Tocopherol Acetate, Butylated Hydroxytoluene.	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away	

Manufactured for:
True Marker Pharmaceuticals, Inc.
Phoenix, AZ 85040

TOLNAFI-AL

tolnaftate liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83592-480
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 mL

Inactive Ingredients

Ingredient Name	Strength
HELIANTHUS ANNUUS FLOWERING TOP (UNII: BKJ0J3D1BP)	
VITIS VINIFERA FRUIT OIL (UNII: YQ5Q4Y2Z8U)	
PEPPERMINT (UNII: V95R5KMY2B)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83592-480-30	1 in 1 CARTON	08/01/2023	
1		30 mL in 1 BOTTLE, GLASS; Type 0: Not a		

1		Combination Product		
2	NDC:83592-480-01	2 in 1 CARTON	08/01/2023	
2		30 mL in 1 BOTTLE, GLASS; 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	08/01/2023	

Labeler - True Marker Pharmaceuticals, Inc. (119046582)

Revised: 11/2023

True Marker Pharmaceuticals, Inc.