

SANAFITIL- tolnaftate cream
Promex LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Active Ingredients

Tolnaftate 1%

Purpose

Antifungal

Uses

- clinically proven to cure most athlete's foot (tinea pedis) and ringworm (tinea corporis)
- helps prevent most athlete's foot from recurring when used daily
- effectively soothes and relieves symptoms of athlete's foot, including itching, burning and cracking

Warnings

For external use only

When using this product

avoid contact with the 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 for 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

Inactive ingredients

Carbomer, Cetyl alcohol, Chlorocresol, Dibasic sodium phosphate hydrate, Glycerin, Glyceryl monostearate, Light liquid paraffin, Myristoyl/palmitoyl oxostearamide/arachamide MEA, PEG-15 glyceryl stearate, Stearic acid, Water

Principal Display Panel

50 years fighting fungus!



SANAFITIL®

ANTI-HONGOS ANTIFUNGAL

50 años
combatiendo los hongos!

SANAFITIL®

SANAFITIL®

 | CREMA ANTIHONGOS
| ANTIFUNGAL CREAM

SANAFITIL
ANTI-HONGOS
ANTIFUNGAL

LOT & EXP.

NET WEIGHT / PESO NETO : 1 OZ (28.35 g)

PC-217.00

Pro-Mex®, LLC
500 NE 190th St.
Miami, FL 33179
Toll Free: 1-855-877-6639

Made in Korea / Fabricado en Corea



Datos del medicamento		Drug Facts	
Propósito Antihongos	Ingredientes Activos Tolnaftate 1%	Active Ingredients (in each gram) 1% Antifungal	Purpose Antifungal
Usos • Clínicamente probado para curar las mayorías de los casos de pie de atleta, tinea inguinal y tinea corporis. • Ayuda a prevenir que el Pie de Atleta vuelva a aparecer cuando se usa diariamente.	Advertencia: • Sólo para uso externo. • Cuando use este producto evite el contacto con ojos.	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). • Pay special attention to the space between the toes, wear well fitting, ventilated shoes and change shoes & socks at least once daily. • To prevent athlete's foot, apply once or twice daily (morning and/or night). • This product is not effective on the scalp or nails. Other information: Store between 36° - 86° F (2° - 30° C)
Instrucciones: • Limpie la zona afectada y seque. • Aplique una capa delgada sobre el área afectada dos veces al día (mañana y noche). • Cambie bien ajustados y bien ventilados. Cambie de zapatos y medias por lo menos una vez al día. • Use el producto diariamente 4 semanas; si la condición persiste por más tiempo, consulte a un médico. • Para prevenir el pie de atleta, aplique una o dos veces al día (mañana y/o noche). • Producto no es efectivo en el cuero cabelludo o las uñas.	Uso en niños: • No utilizar en niños menores de 2 años de edad, excepto bajo la recomendación y la supervisión de un médico. MANTENER FUERA DEL ALCANCE DE LOS NIÑOS. En caso de ingestión, obtenga ayuda médica o póngase en contacto con un centro de toxicología de inmediato.	Other ingredients: carbomer, cetyl alcohol, chlorocresol dibasic sodium phosphate hydrate, glycerin, glyceryl monostearate, light liquid paraffin, myristoyl/palmitoyl oxostearamide/aracha-mide MCA, PEG-15 glyceryl stearate, purified water, stearyl acid Other ingredients: carbomero, alcohol cetílico, clorocresol hidrato de fosfato de sodio, glicerina, glicero monoestearato de glicerilo, parafina líquida ligera, mistilol / oxidostearamida/arachamida / arachamida MCA, PEG-15 estearato de glicerilo, agua purificada, ácido esteárico	

SANAFITIL®

Other Information

- store between 36° and 86°F (2° and 30°C)

SANAFITIL

tolnaftate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58988-0017
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
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PARAFFIN (UNII: I9O0E3H2ZE)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
WATER (UNII: 059QF0KO0R)	
CHLOROCRESOL (UNII: 36W53O7109)	
SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74)	
MYRISTOYL/PALMITOYL OXOSTEARAMIDE/ARACHAMIDE MEA (UNII: 1211AIM8G7)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58988-0017-1	1 in 1 BOX		
1		28.35 g in 1 TUBE		

50 years fighting fungus!



SANAFITIL®

ANTI-HONGOS
ANTIFUNGAL

50 años
combatiendo los hongos!

SANAFITIL®

SANAFITIL®

CREMA ANTIHONGOS
ANTIFUNGAL CREAM

SANAFITIL
ANTI-HONGOS
ANTIFUNGAL

LOT & EXP.

NET WEIGHT / PESO NETO : 1 OZ (28.35 g)

PC-217.00

Pro-Mex®, LLC
500 NE 190th St.
Miami, FL 33179
Toll Free: 1-855-877-6639



Drug Facts	
Active Ingredients (in each gram) Tolterate 1% Amfingal	Uses: • clinically proven to cure most athlete's foot (tinea pedis) and ringworm (tinea corporis) • helps prevent most athlete's foot from recurring when used daily • effectively soothes and relieves symptoms of athlete's foot, including itching, burning and cracking
Warnings: • For external use only. • When using this product avoid contact with eyes	Directions: If swallowed, get medical help or contact a poison control center right away. • wash affected area and dry thoroughly • apply a thin layer over affected area twice daily (morning and night) • for athlete's foot, pay special attention to the space between the toes, wear well fitting, ventilated shoes and change shoes & socks at least once daily • use daily for 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
Other Information: Store between 36° - 86° F (2° - 30° C)	Other Ingredients: carbomer, cetyl alcohol, chlorocresol dibasic sodium phosphate hydrate, glycerol, glyceryl monostearate, light liquid paraffin, myristicyl/palmiticlyl oxostearamide/arachide-mide MEA, PEG-15 glyceryl stearate, purified water, stearyl acid
Other Information: Almacenar a 36° - 86° F (15° - 30° C) • producto no es efectivo en el cuero cabelludo o las uñas. • use el producto diariamente 4 semanas; si la condición persiste por más tiempo, consulte a un médico • para prevenir el pie de atleta, aplique una o dos veces al día (mañana y/o noche)	Other Ingredients: carbomero, alcohol cetílico, clorocresol hidrato de fosfato de sodio oxostearamida/palmitoil / arachemida MEA, PEG-15 estearato de glicerilo, agua purificada, ácido esteárico
Advertencia: • Evite los síntomas del pie de atleta, incluso la picazón, ardor, grietas y descamación • Solo para uso externo. • Cuando use este producto evite el contacto con ojos	Advertencia: • Evite los síntomas del pie de atleta, incluso la picazón, ardor, grietas y descamación • Únicamente probado para curar las mayores de los casos de pie de atleta, tina inguinal y tina corporis • clínicamente probado para curar las mayores de los casos de pie de atleta, tina inguinal y tina corporis
Suspensión el uso y consulte a un médico si: • ocurre irritación • No ocurre mejoría en 4 semanas de tratamiento	Indicaciones: • limpie la zona afectada y seque. • aplique una capa delgada sobre el área afectada dos veces al día (mañana y noche) • para el pie de atleta, preste atención especial al espacio entre los dedos de los pies. Use zapatos bien ajustados y bien ventilados. Cambie de zapatos y medias por lo menos una vez al día. • use el producto diariamente 4 semanas; si la condición persiste por más tiempo, consulte a un médico • para prevenir el pie de atleta, aplique una o dos veces al día (mañana y/o noche)
MANTENER FUERA DEL ALCANCE DE LOS NIÑOS. En caso de ingestión, obtenga ayuda médica o póngase en contacto con un centro de toxicología de inmediato.	KEEP OUT OF REACH OF CHILDREN. Do not use on children under 2 years of age except under the advice and supervision of a doctor. • There is no improvement within 4 weeks • Irritation occurs
No utilizar en niños menores de 2 años de edad, excepto bajo la recomendación y la supervisión de un médico.	Do not use on children under 2 years of age except under the advice and supervision of a doctor. • There is no improvement within 4 weeks • Irritation occurs

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
--------------------	--	----------------------	--------------------

Labeler - Promex LLC (789974388)

Revised: 1/2015

Promex LLC