

## **SANAFITIL CREMA- 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	
<b>Propósito</b> Antihongos	<b>Ingredientes Activos</b> Tolnaftate 1%	<b>Active Ingredients (in each gram)</b> 1% Antifungal	<b>Purpose</b> Antifungal
<b>Usos</b> • Clínicamente probado para curar las mayoría de los casos de pie de atleta, tina inguinal y tina corporis. • Ayuda a prevenir que el Pie de Atleta vuelva a aparecer cuando se usa diariamente.	<b>Advertencia:</b> • Sólo para uso externo. • Cuando use este producto evite el contacto con ojos.	<b>Warnings:</b> • For external use only. • When using this product avoid contact with eyes.	<b>Uses:</b> • 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.
<b>Instrucciones:</b> • Limpie la zona afectada y seque. • Aplique una capa delgada sobre el área afectada dos veces al día (mañana y noche). 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) un producto no es efectivo en el cuero cabelludo o las uñas.	<b>Other information:</b> Store between 36° - 86° F (2° - 30° C).	<b>Directions:</b> • 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.	<b>Other ingredients:</b> 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.
<b>Otros ingredientes:</b> carbomero, alcohol cetílico, clorocresol hidrato de fosfato de sodio, glicerina, glicerilo monoestearato de glicerilo, parafina líquida ligera, mistilo / ácido esteárico.	<b>Other ingredients:</b> 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.		

# SANAFITIL®

### Other Information

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

## SANAFITIL CREMA

tolnaftate cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58988-1600
<b>Route of Administration</b>	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: 059QF0K00R)	
CHLOROCRESOL (UNII: 36W53O7109)	
SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74)	
MYRISTOYL/PALMITOYL OXOSTEARAMIDE/ARACHAMIDE MEA (UNII: 1211AIM8G7)	

### Product Characteristics

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58988-1600-2	1 in 1 BOX		
1		28.35 g in 1 TUBE		



# SANAFITIL®

50 years fighting fungus!

## 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	
<b>Active Ingredients (in each gram)</b> Tolnaftate 1% Amfingal	<b>Uses:</b> • 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
<b>Warnings:</b> • For external use only. • When using this product avoid contact with eyes	<b>Directions:</b> • 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
<b>Other Information:</b> Store between 36° - 86° F (2° - 30° C)	<b>Other Ingredients:</b> 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 alcohol
<b>Other Information:</b> 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)	<b>Other Ingredients:</b> carbomero, alcohol cetílico, clorocresol hidrato de fosfato de sodio disódico, glicerina, monoestearato de glicerilo, parafina líquida ligera, mistolol / oxostearamida/araquidamida de metilacetato, agua purificada, ácido estearílico
<b>Advertencia:</b> • Evite los síntomas del pie de atleta, incluso la picazón, ardor, grietas y descamación • Sólo para uso externo. • Cuando use este producto evite el contacto con ojos	<b>Indicaciones:</b> • 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
<b>Propósito</b> Antihongos	<b>Mantener fuera del alcance de los niños.</b> En caso de ingestión, obtenga ayuda médica o póngase en contacto con un centro de toxicología de inmediato. No utilizar en niños menores de 2 años de edad, excepto bajo la recomendación y la supervisión de un médico. • Interruption occurs • There is no improvement within 4 weeks • Stop use and ask a doctor if: • Interruption occurs • There is no improvement within 4 weeks • When using this product avoid contact with eyes
<b>Ingredientes Activos</b> Tolnaftate 1% Amfingal	<b>Propósito</b> Antihongos
<b>Datos del medicamento</b>	<b>Propósito</b> Antihongos

### Marketing Information

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

**Labeler** - Promex LLC (789974388)

Revised: 1/2015

Promex LLC