

GADADERM ANTIFUNGAL- tolnaftate cream
Gadal Laboratories Inc

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.

Active Ingredient	Purpose
Tolnaftate 1%	Antifungal

▯Purpose
Antifungal

▯Uses

- ▯Proven clinically to cure most:
- Athlete's foot (tinea pedis)
- Ringworm (tinea corporis)
- Effectively soothes and relieves:
- itching
- burning
- cracking
- Helps prevent most athlete's foot from coming back 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 the eyes.

Stop use and ask a doctor if

- irritation occurs
- There is no improvement within 4 weeks.

Keep out of reach of children. 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 over the 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 lasts longer, ask a doctor.
- to prevent athlete's foot, apply to the feet once or twice daily (morning and/or night)
- this product is not effective on the scalp or nails

▯Inactive ingredients▯ Mineral oil, propylene glycol, cety stearyl alcohol, purified water, cetareth-6, stearyl alcohol, PEG-20 cetyl/stearyl ether, methylparaben, sodium m-bisulfite, propylparaben

SSS Group LLC.

Miami, Fl 33186

Drug Facts		Información General	
Active Ingredient	Purpose	Ingrediente Activo	Propósito
Tolnaftate 1%.....	Antifungal	Tolnaftate 1%.....	Antifungal
Uses • Proven clinically to cure most: • Athlete's foot (tinea pedis) • Ringworm (tinea corporis) • Effectively soothes and relieves: • Itching • burning • cracking • Helps prevent most athlete's foot from coming back with daily use.		Usos • Clínicamente probado para curar la mayoría de: • Pie de atleta (tinea pedis) • tiña (tinea corporis) • Efectivamente calma y alivia: • el picor • la quemazón • las grietas • Ayuda a prevenir la mayoría de pie de atleta con el uso diario.	
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. Stop use and ask a doctor if • Irritation occurs • There is no improvement within 4 weeks. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.		Avisos Para uso externo solamente. No use en niños menores de 2 años de edad excepto si es indicado por un medico. Evite el contacto con los ojos cuando use este producto. Detenga el uso y consulte a su medico • si surge irritación. • si la condición no mejora en 4 semanas. Mantenga fuera del alcance de los niños. En caso de ingestión accidental busque asistencia médica o llame al Centro de Tratamiento por Envenenamiento de inmediato.	
Directions • Clean the affected area and dry thoroughly. • apply a thin layer over the 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 lasts longer, ask a doctor. • to prevent athlete's foot, apply to the feet once or twice daily (morning and/or night) • this product is not effective on the scalp or nails.		Instrucciones • lave el área afectada y sequen bien. • aplique una capa fina sobre el área afectada dos veces al día (mañana y noche) • supervise a los niños al usar este producto. • para combatir el pie de atleta ponga especial atención al área entre los dedos: use zapatos cómodos y bien ventilados, cambie medias y zapatos una vez al día. • use diariamente por 4 semanas. Si la condición persiste, consulte a su medico. • para prevenir el pie de atleta, aplique a los pies una o dos veces al día (mañana y noche). • este producto no es efectivo en las uñas o cuero cabelludo.	
Other information • store between 20° - 25° C (68° -77°F). Keep box for complete instructions and labeling.		Información adicional • almacene entre 20° - 25° C (68° -77°F). Guarde la caja para instrucciones.	
Inactive ingredients: mineral oil, propylene glycol, cetyl stearyl alcohol, purified water, cetearth-6, stearyl alcohol, peg-20 cetyl/stearyl ether, methylparaben, sodium m-bisulfite, propylparaben.		Ingredientes Inactivos: aceite mineral, propilen glicol, alcohol ceto estearílico, agua purificada, cetearth-6, stearyl alcohol, peg-20 cetyl/stearyl eter, metilparabeno, metabisulfito de sodio, propil parabeno.	

Drug Facts (continued)	Información General (continuación)
Questions or comments? Please call 305-382-3288 (M-F 8:00-5:00 pm EST)	Preguntas o comentarios? Favor de llamar al 305-382-3288 (L-V 8:00-5:00 pm EST)

Manufactured by: Gadal Laboratories, Inc. • Miami, FL 33186 • www.gadalaboratories.com

Distributed by: SSS Group, LLC. • Miami, FL 33186

Net Wt 28g (1 oz)

Keep box for complete instructions and labeling.
 Guarde la caja para instrucciones

1% Tolnaftate Cream

Antifungal
 Cures Most Athlete's Foot

Gadaderm®

Net Wt 28g (1 oz)

Keep box for complete instructions and labeling.
 Guarde la caja para instrucciones

1% Tolnaftate Cream

Antifungal
Cures Most Athlete's Foot

CREAM

Cura la mayoría de los Hongos en los Pies Cures most of athlete's Foot

NDC 53113-263-01

Gadaderm[®]

GADADERM ANTIFUNGAL

tolnaftate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53113-263
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
MINERAL OIL (UNII: T5L8T28FGP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)	
WATER (UNII: 059QF0KO0R)	
CETEARETH-6 (UNII: 2RJS3559D3)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
SODIUM BISULFITE (UNII: TZX5469Z6I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53113-263-01	1 in 1 BOX		
1		28 g in 1 TUBE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	01/01/2013	

Labeler - Gadal Laboratories Inc (841305639)

Revised: 9/2013

Gadal Laboratories Inc