

**DERMAN ANTIFUNGAL- zinc undecylenate cream**  
**Teresa Cecena DBA Genesis**

*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 INGREDIENTS.**

Zinc undecylenate 18%  
undecylenic acid 5%

**PURPOSE**

Antifungal

**USES**

For the treatment of athlete's foot. Relieves itching-scaling-cracking-burning.

**AVOID CONTACT WITH EYES**

Keep this and all drugs out of the reach of children. In case of accidental ingestion, seek professional assistance or contact a poison control center immediately.

Do not use in pregnancy and children under 2 years of age unless directed by a physician.

For external use only

In case of accidental ingestion seek professional assistance or contact a poison control center immediately.

Wash 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 physician. Supervise children in the use of this product. Pay special attention to space between the toes, wear well fitting, ventilated shoes. Change shoes and socks at least once daily. Use daily for 4 weeks. If condition persists, consult a physician.

This product is not effective on the scalp or nails.

Polyethylene Glycol 500, polyethylene glycol 4000, water, glycerin, cetyl alcohol, propylene glycol, zinc stearate, nonyl phenol sulfate, sodium bisulfite.

# DERMAN<sup>®</sup>

## ANTIFUNGAL CREAM

FOR THE TREATMENT OF ATHLETE'S FOOT  
NET WT. 0.88 OZ (25 g)



**AGAINST: • Itching • Peeling • Soothes Cracking • Burning**

**DIRECTIONS :** Wash 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 physician. Supervise children in the use of this product. Pay special attention to spaces between the toes, wear well fitting, ventilated shoes. Change shoes and socks at least once daily. Use daily for 4 weeks. If condition persists, consults a physician. This product is not effective on the scalp or nails. **WARNING: FOR EXTERNAL USE ONLY.** Do not use on children under 2 years of age unless directed by a physician. Avoid contact with the eyes **KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN. IN CASE OF ACCIDENTAL INGESTION. SEEK PROFESSIONAL ASSISTANCE OR CONTACT A POISON CONTROL CENTER IMMEDIATELY.**

**ACTIVE INGREDIENTS:** Each 100 grams contain 18.0 g Zinc Undecylenate and 5.0 g Undecylenic acid.

**INACTIVE INGREDIENTS:** Polyethylene Glycol 500, Polyethylene Glycol 4000, Water, Glycerin, Cetyl Alcohol, Propylene Glycol, Zinc Stearate, Nonyl Phenol Sulfate, Sodium Bisulfite.

**MANUFACTURED BY** FARMAQRO, S.A. de C.V., CALLE 2 NO. 42, PARQUE INDUSTRIAL BENITO JUÁREZ, SANTIAGO DE QUERÉTARO, QRO. C.P. 76120

**DISTRIBUTED BY: GENESIS. SAN YSIDRO CA**

www.derman.com.mx

Lot. No.:  
Expiration Date:

KEEP THIS AND ALL DRUGS OUT OF REACH OF CHILDREN

Wash 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 physician. Supervise children in the use of this product Pay special attention to space between the toes, wear well fitting, ventilated shoes. Change shoes and socks at least once daily. Use daily for 4 weeks. If condition persists, consults a physician.

This product is not effective on the scalp or nails

### DERMAN ANTIFUNGAL

zinc undecylenate cream

#### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69772-125
Route of Administration	TOPICAL		

#### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
UNDECYLENIC ACID (UNII: K3D86KJ24N) (UNDECYLENIC ACID - UNII:K3D86KJ24N)	UNDECYLENIC ACID	5 g in 100 g
ZINC UNDECYLENATE (UNII: 388VZ25DUR) (UNDECYLENIC ACID - UNII:K3D86KJ24N)	ZINC UNDECYLENATE	18 g in 100 g

#### Inactive Ingredients

Ingredient Name	Strength
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYETHYLENE GLYCOL 500 (UNII: 761NX2Q08Y)	
POLYETHYLENE GLYCOL 4000 (UNII: 4R4HF16D95)	
GLYCERIN (UNII: PDC6A3C0OX)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	
ZINC STEARATE (UNII: H92E6QA4FV)	
SODIUM BISULFITE (UNII: TZX5469Z6I)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69772-125-02	1 in 1 CARTON	05/14/2015	
1	NDC:69772-125-01	25 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:69772-125-03	1 in 1 CARTON	05/20/2015	
2		50 g in 1 TUBE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	05/14/2015	

**Labeler** - Teresa Cecena DBA Genesis (078760958)

**Registrant** - Teresa Cecena (078760958)

### Establishment

Name	Address	ID/FEI	Business Operations
Teresa Cecena DBA Genesis		078760958	relabel(69772-125)

### Establishment

Name	Address	ID/FEI	Business Operations
COMPANIA INTERNACIONAL DE COMERCIO, S.A.P.I.DE C.V.		815039995	manufacture(69772-125)

Revised: 5/2015

Teresa Cecena DBA Genesis