

**DERMAN ANTIFUNGAL- zinc undecylenate cream**  
**Compania Internacional de Comercio, S.A.P.I de C.V.**

*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.*

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**Derman Antifungal**

**Active Ingredients.**

Zinc undecylenate 18%

Undecylenic acid 5%

**Purpose**

Antifungal

**Uses**

For the treatment of athlete's foot.

**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 or if there is no improvement within 4 weeks.

**Keep out of the reach of children.**

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

**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 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.
- Use daily for 4 weeks.
- If condition persists, consult a physician.
- This product is not effective on the scalp or nails.

***Inactive ingredients***

Cetyl alcohol, Glycerin, Polyethylene Glycol 500, Polyethylene glycol 4000, Propylene glycol, Sodium bisulfite, Sodium laureth sulfate, water, Zinc stearate.

### Derman Antifungal (54312-125-01)

<p><b>Drug Facts</b> (continued)</p> <p><b>Warnings</b> <b>For external use only.</b> <b>Do not use</b> on children under 2 years of age unless directed by a doctor. <b>When using this product</b> avoid contact with the eyes. <b>Stop use and ask a doctor</b> if irritation occurs or if there is no improvement within 4 weeks. <b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.</p> <p><b>Directions</b> ■ Wash 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. ■ 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.</p>	<p><b>Manufactured by</b> FARMAQRO, S.A. DE C.V., Calle 2 No. 42, Parque Industrial Benito Juárez, Santiago de Querétaro, Qro, C.P. 76120, México</p> <p><b>Distributed by</b> Taisho Pharmaceutical California, Inc.</p> <p><b>Made in Mexico</b></p>	<p><b>ANTIFUNGAL CREAM</b> <b>DERMAN</b><sup>®</sup> UNDECYLENIC ACID . ZINC UNDECYLENATE</p> <p>Lot. No.: Expiration Date:</p>				
<p><b>Drug Facts</b> (continued)</p> <p>■ Use daily for 4 weeks. ■ If condition persists longer, consult a doctor. ■ This product is not effective on the scalp or nails.</p> <p><b>Inactive ingredients:</b> Cetyl alcohol, Glycerin, Polyethylene glycol 500, Polyethylene glycol 4000, Propylene glycol, Sodium bisulfite, Sodium laureth sulfate, Water, Zinc stearate.</p> <p>TO REPORT A SERIOUS ADVERSE EVENT CONTACT 3528 Torrance Blvd, Suite #320 Torrance, CA 90503</p>	 <p>3 54312 22501 0</p>	<p>30113-03</p>				
<p><b>ANTIFUNGAL CREAM</b> <b>UNDECYLENIC ACID . ZINC UNDECYLENATE</b></p> <p><b>DERMAN</b><sup>®</sup></p> <p><b>ANTIFUNGAL CREAM</b> <b>UNDECYLENIC ACID . ZINC UNDECYLENATE</b></p> <p>FOR THE TREATMENT OF ATHLETE'S FOOT</p> <p><b>NET WT. 0.88 OZ (25 g)</b></p> 						
<p><b>Drug Facts</b></p> <table border="0"><tr><td><b>Active ingredients</b></td><td><b>Purpose</b></td></tr><tr><td>Undecylenic acid 5% } Zinc undecylenate 18% }</td><td>Antifungal</td></tr></table> <p><b>Use</b> For the treatment of athlete's foot.</p>			<b>Active ingredients</b>	<b>Purpose</b>	Undecylenic acid 5% } Zinc undecylenate 18% }	Antifungal
<b>Active ingredients</b>	<b>Purpose</b>					
Undecylenic acid 5% } Zinc undecylenate 18% }	Antifungal					

# DERMAN<sup>®</sup>

ANTIFUNGAL CREAM  
UNDECYLENIC ACID . ZINC UNDECYLENATE

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



30112-V3

This unit is packaged in an outer container and is not labeled for retail sale. Please see outer container for complete drug facts information. **Active ingredients:** Undecylenic acid 5%; Zinc undecylenate 18%. **Purpose:** Antifungal. **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 or if 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:** Wash 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. 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, consult a doctor. This product is not effective on the scalp or nails. **Inactive ingredients:** Cetyl alcohol, Glycerin, Polyethylene glycol 500, Polyethylene glycol 4000, Propylene glycol, Sodium bisulfite, Sodium laureth sulfate, Water, Zinc stearate.

**TO REPORT A SERIOUS ADVERSE EVENT CONTACT** 3528 Torrance Blvd. Suite #320 Torrance, CA 90503

**Manufactured by** FARMAQRO, S.A. DE C.V., Calle 2 No. 42, Parque Industrial Benito Juárez, Santiago de Querétaro, Qro. C.P. 76120, México. **Distributed by** Taisho Pharmaceutical California, Inc. **Made in Mexico.**

Lot No.:  
Expiration Date:

**Drug Facts** (continued)

**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 or if 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**

- Wash the affected area and dry thoroughly.
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- 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.

Lot. No.:  
Expiration Date:

**Drug facts** (continued)

- Use daily for 4 weeks.
- If condition persists longer, consult a doctor.
- This product is not effective on the scalp or nails.

**Inactive ingredients:** Cetyl alcohol, Glycerin, Polyethylene glycol 500, Polyethylene glycol 4000, Propylene glycol, Sodium bisulfite, Sodium laureth sulfate, Water, Zinc stearate.

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MADE IN MEXICO

30541-V4

UNDECYLENIC ACID • ZINC UNDECYLENATE  
**DERMAN**<sup>®</sup>  
ANTIFUNGAL CREAM

**DERMAN**<sup>®</sup>

ANTIFUNGAL CREAM  
UNDECYLENIC ACID • ZINC UNDECYLENATE

FOR THE TREATMENT OF ATHLETE'S FOOT

NET WT. 0.88 OZ (25 g)



**Drug Facts**

**Active ingredients**

Active ingredients	Purpose
Undecylenic acid 5%	Antifungal
Zinc undecylenate 18%	Antifungal

**Use** For the treatment of athlete's foot.



54312 22501 0

# DERMAN<sup>®</sup>

ANTIFUNGAL CREAM  
UNDECYLENIC ACID • ZINC UNDECYLENATE

FOR THE TREATMENT OF ATHLETE'S FOOT

**NET WT. 0.88 OZ (25 g)**



This unit is packaged in an outer container and is not labeled for retail sale. Please see outer container for complete drug facts information. **Active ingredients:** Undecylenic acid 5%; Zinc undecylenate 18%. **Purpose:** Antifungal. **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 or if 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:** Wash 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. 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, consult a doctor. This product is not effective on the scalp or nails. **Inactive ingredients:** Cetyl alcohol, Glycerin, Polyethylene glycol 500, Polyethylene glycol 4000, Propylene glycol, Sodium bisulfite, Sodium laureth sulfate, Water, Zinc stearate. **Distributed by** Taisho Pharmaceutical California, Inc. 3528 Torrance Blvd, Suite # 320 Torrance, CA 90503 U.S.A. **MADE IN MEXICO**

30543-V4

Lot. No.:  
Expiration Date:

**Derman Antifungal (54312-125-02)**

**Drug Facts** (continued)

**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 or if 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**

- Wash 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.
- 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.

**Manufactured by**  
 FARMAQRO, S.A. DE C.V.,  
 Calle 2 No. 42, Parque  
 Industrial Benito Juárez,  
 Santiago de Querétaro,  
 Qro. C.P. 76120, México.  
**Distributed by**  
 Taisho Pharmaceutical  
 California, Inc.

**Made in Mexico.**

ANTIFUNGAL CREAM  
**DERMAN**<sup>®</sup>  
 UNDECYLENIC ACID • ZINC UNDECYLENATE

**Drug Facts** (continued)

- Use daily for 4 weeks. ■ If condition persists longer, consult a doctor.
- This product is not effective on the scalp or nails.

**Inactive ingredients:** Cetyl alcohol, Glycerin, Polyethylene glycol 500, Polyethylene glycol 4000, Propylene glycol, Sodium bisulfite, Sodium laureth sulfate, Water, Zinc stearate.

TO REPORT A SERIOUS ADVERSE EVENT CONTACT 3528 Torrance Blvd, Suite #320 Torrance, CA 90503



30110-V3

# DERMAN<sup>®</sup>

ANTIFUNGAL CREAM  
UNDECYLENIC ACID • ZINC UNDECYLENATE

FOR THE TREATMENT OF ATHLETE'S FOOT

NET WT. 1.76 OZ (50 g)



ANTIFUNGAL CREAM  
**DERMAN**<sup>®</sup>  
 UNDECYLENIC ACID • ZINC UNDECYLENATE

**Drug Facts**

**Active ingredients**

Undecylenic acid 5%  
Zinc undecylenate 18%

**Purpose**

Antifungal

**Use** For the treatment of athlete's foot.

# DERMAN<sup>®</sup>

ANTIFUNGAL CREAM  
UNDECYLENIC ACID • ZINC UNDECYLENATE

FOR THE TREATMENT OF ATHLETE'S FOOT

NET WT. 1.76 OZ (50 g)



This unit is packaged in an outer container and is not labeled for retail sale. Please see outer container for complete drug facts information.

**Active Ingredients:** Undecylenic acid 5%; Zinc undecylenate 18%. **Purpose:** Antifungal. **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 or if 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:** Wash 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. 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, consult a doctor. This product is not effective on the scalp or nails. **Inactive Ingredients:** Cetyl alcohol, Glycerin, Polyethylene glycol 500, Polyethylene glycol 4000, Propylene glycol, Sodium bisulfite, Sodium laureth sulfate, Water, Zinc stearate.

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**MADE IN MEXICO**

30544-V4

Lot. No.:  
Expiration Date:

**Drug Facts** (continued)

**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 or if 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** ■ Wash 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.
- 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.

Lot. No.:  
Expiration Date:

**Drug facts** (continued)

- Use daily for 4 weeks. ■ If condition persists longer, consult a doctor.
- This product is not effective on the scalp or nails.

**Inactive ingredients:** Cetyl alcohol, Glycerin, Polyethylene glycol 500, Polyethylene glycol 4000, Propylene glycol, Sodium bisulfite, Sodium laureth sulfate, Water, Zinc stearate.

30542-V4

DISTRIBUTED BY Taisho Pharmaceutical California Inc. 3528 Torrance Blvd, Suite #320 Torrance, CA 90503 U.S.A.  
MADE IN MEXICO

ANTIFUNGAL CREAM  
**DERMAN**<sup>®</sup>  
UNDECYLENIC ACID • ZINC UNDECYLENATE

**DERMAN**<sup>®</sup>

ANTIFUNGAL CREAM  
UNDECYLENIC ACID • ZINC UNDECYLENATE

FOR THE TREATMENT OF ATHLETE'S FOOT



NET WT. 1.76 OZ (50 g)

**Drug Facts**

**Active ingredients**

Undecylenic acid 5%	.....	<b>Purpose</b>	Antifungal
Zinc undecylenate 18%	.....		Antifungal

**Use** For the treatment of athlete's foot.



**DERMAN**<sup>®</sup>

ANTIFUNGAL CREAM  
UNDECYLENIC ACID • ZINC UNDECYLENATE

FOR THE TREATMENT OF ATHLETE'S FOOT

NET WT. 1.76 OZ (50 g)



30109-V3

This unit is packaged in an outer container and is not labeled for retail sale. Please see outer container for complete drug facts information.

**Active Ingredients:** Undecylenic acid 5%; Zinc undecylenate 18%. **Purpose:** Antifungal. **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 or if 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:** Wash 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. 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, consult a doctor. This product is not effective on the scalp or nails. **Inactive Ingredients:** Cetyl alcohol, Glycerin, Polyethylene glycol 500, Polyethylene glycol 4000, Propylene glycol, Sodium bisulfite, Sodium laureth sulfate, Water, Zinc stearate.

**TO REPORT A SERIOUS ADVERSE EVENT CONTACT** 3528 Torrance Blvd, Suite #320 Torrance, CA 90503.

**Manufactured by** FARMAQRO, S.A. DE C.V., Calle 2 No. 42, Parque Industrial Benito Juárez, Santiago de Querétaro, Qro. C.P. 76120, México. **Distributed by** Taisho Pharmaceutical California, Inc. **Made in Mexico.**

Lot. No.:  
Expiration Date:

zinc undecylenate cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:54312-125
<b>Route of Administration</b>	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: 388 VZ25DUR) (UNDECYLENIC ACID - UNII:K3D86KJ24N)	ZINC UNDECYLENATE	18 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 500 (UNII: 761NX2Q08Y)	
POLYETHYLENE GLYCOL 4000 (UNII: 4R4HF16D95)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM BISULFITE (UNII: TZX5469Z6I)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
WATER (UNII: 059QF0KO0R)	
ZINC STEARATE (UNII: H92E6QA4FV)	

### Product Characteristics

<b>Color</b>	white	<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:54312-125-01	1 in 1 CARTON	08/12/2013	
1		25 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:54312-125-02	1 in 1 CARTON	08/12/2013	
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	08/12/2013	



**Labeler** - Compania Internacional de Comercio, S.A.P.I de C.V. (815039995)

**Registrant** - Compania Internacional de Comercio, S.A.P.I de C.V. (815039995)

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Compania Internacional de Comercio, S.A.P.I de C.V.		815039995	manufacture(54312-125)

Revised: 5/2019

Compania Internacional de Comercio, S.A.P.I de C.V.