

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

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)

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

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.

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

DERMAN[®]

ANTIFUNGAL CREAM
UNDECYLENIC ACID . ZINC UNDECYLENATE

FOR THE TREATMENT OF ATHLETE'S FOOT

NET WT. 0.88 OZ (25 g)

DERMAN[®]
ANTIFUNGAL CREAM
UNDECYLENIC ACID . ZINC UNDECYLENATE

Drug Facts

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

Use For the treatment of athlete's foot.

DERMAN[®]

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.

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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.

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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

DERMAN[®]

ANTIFUNGAL CREAM
UNDECYLENIC ACID • ZINC UNDECYLENATE

FOR THE TREATMENT OF ATHLETE'S FOOT

NET WT. 0.88 OZ (25 g)

**Drug Facts****Active ingredients**

Undecylenic acid 5%

Zinc undecylenate 18%

Purpose

Antifungal

Antifungal

Use For the treatment of athlete's foot.



UNDDECYLENIC ACID • ZINC UNDECYLENATE
DERMAN[®]
ANTIFUNGAL CREAM

DERMAN[®]

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.
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ANTIFUNGAL CREAM
DERMAN®
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®

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%
Zinc undecylenate 18%

Purpose

Antifungal

Use For the treatment of athlete's foot.

DERMAN®

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.

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

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.

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- 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.

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

30542-V4

DERMAN[®]

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%

Zinc undecylenate 18%

Purpose

Antifungal

Antifungal

Use For the treatment of athlete's foot.



DERMAN[®]

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.

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Lot No.:
Expiration Date:

DERMAN ANTIFUNGAL

zinc undecylenate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54312-125
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
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 500 (UNII: 761NX2Q08Y)	
POLYETHYLENE GLYCOL 4000 (UNII: 4R4HFI6D95)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM BISULFITE (UNII: TZX5469Z6I)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
WATER (UNII: 059QF0KO0R)	
ZINC STEARATE (UNII: H92E6QA4FV)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

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 Drug	M005	08/12/2013	

Labeler - Compania Internacional de Comercio, S.A.P.I de C.V. (822165213)

Registrant - Compania Internacional de Comercio, S.A.P.I de C.V. (822165213)

Establishment

Name	Address	ID/FEI	Business Operations
Compania Internacional de Comercio, S.A.P.I de C.V.		822165213	manufacture(54312-125)

Revised: 10/2023

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