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.

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

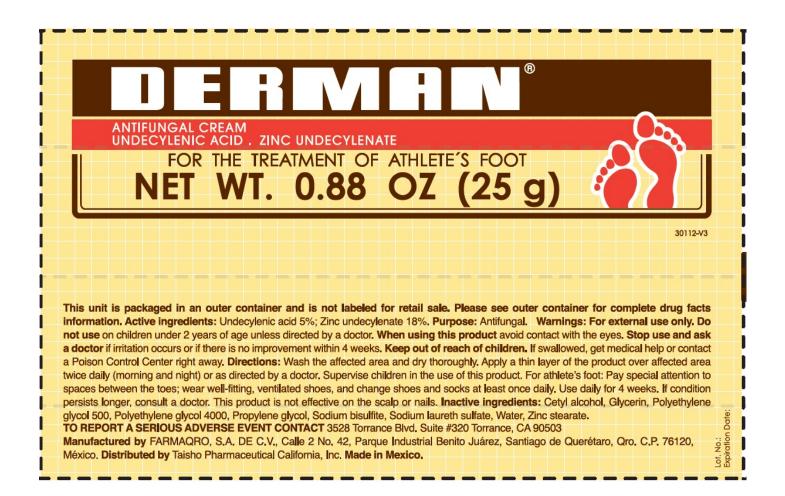
- Wash the affected area and dry thoroughly.
- Apply a thin layer of the product over the affected area twice daily (morning and night) or as directed by a doctor.
- Supervise children in the use of this product.
- For athlete's foot: Pay special attention to spaces between the toes; wear well fitting, ventilated shoes, and change shoes and socks at least once daily.
- Use daily for 4 weeks.
- If condition persists, consults a physician.
- This product is not effective on the scalp or nails.

Inactive ingredients

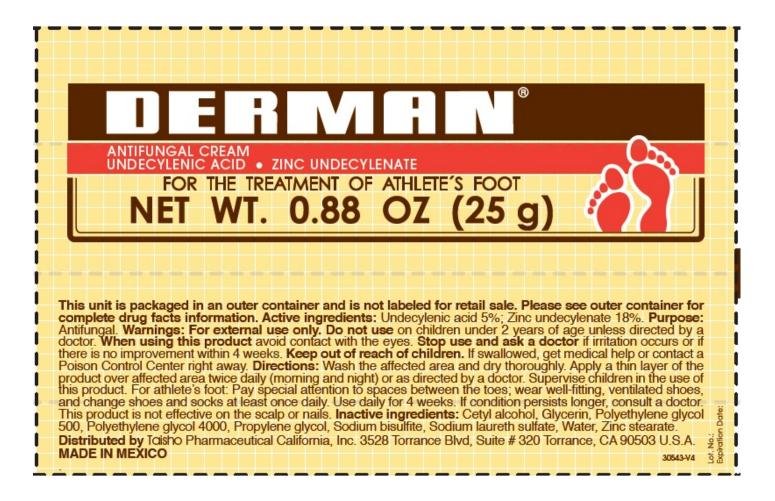
Cetyl alcohol, Glycerin, Polyethylene Glycol 500, Polyethylene glycol 4000, Propylene glycol, Sodium bisulfite, Sodium laureth sulfate, water, Zinc stearate.

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 wel-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 Talsho Pharmaceutical California, Inc. Made in Mexico | ANTIFUNGAL CREAM DEFINICAL CREAM UNDECYLENIC ACID , ZINC UNDECYLENATE Lot. No.: Expiration Date: |
|------------------|---|---|---|
| \nearrow | 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. | | 5. |
| | 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. Sulte #320 Torrance, CA 90503 | 3 5 4 3 1 2 1 2 2 5 0 1 1 0 | 30113-v3 |
| ANTIFUNGAL CREAM | ANTIFUNGAL CREAM UNDECYLENIC ACID. ZINC UNDECYLENATE FOR THE TREATMENT OF ATHLETE'S FOOT NET WT. 0.88 OZ (25) | 5 g) | |
| | Drug Facts Active ingredients Undecylenic acid 5% Zinc undecylenate 18% Use For the treatment of athlete's foot. | <i>Purpose</i> Antifungal | |



| | 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: |
|------------------|---|----------------------------------|
| \sim | 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. | 30541-24 |
| | DISTRIBUTED BY Taisho Pharmaceutical California Inc. 3528 Torrance Blvd, Suite #320 Torrance, CA 90503 U.S.A. MADE IN MÉXICO | |
| | | |
| ANTIFUNGAL CREAM | ANTIFUNGAL CREAM UNDECYLENIC ACID • ZINC UNDECYLENATE | |
| C UNDECYLENATE | FOR THE TREATMENT OF ATHLETE'S FOOT | |
| | Drug Facts | |
| | Active ingredients Purpose Undecylenic acid 5% Antifungal Zinc undecylenate 18% Antifungal | |
| | Use For the treatment of athlete's foot. | |



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. Drug Facts (continued) | 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. | ANTEUNGAL CREAM ANTEUNGAL CREAM DEB TO B TO ANT UNDECVIENC ACID. ZINC UNDECVIENTE |
|--|---|---|---|
| | 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 | Nin 54312 22502 117 | 30110-V3 |
| | ANTIFUNGAL CREAM UNDECYLENIC ACID. ZINC UNDECYLENATE FOR THE TREATMENT OF ATHLETE'S FOOT NET WT. 1.76 02 | 2 (50 g) | |
| | Drug Facts Active ingredients Undecylenic acid 5% Zinc undecylenate 18% Use For the treatment of athlete's foot. | <i>Purpose</i> Antifungal | |
| | DEBRICATION NTIFUNGAL CREAM INDECYLENIC ACID • ZINC UNDECYLENATE FOR THE TREATMENT OF ATHLETE'S FOOT NET WT. 1.76 OZ (50 g |) | |
| Active ing under 2 ye or if there away. Dire as directe well-fitting product is Propylene | Is packaged in an outer container and is not labeled for retail sale. Please see outer container for predients: Undecylenic acid 5%; Zinc undecylenate 18%. Purpose: Antifungal. Warnings: For extern ars of age unless directed by a doctor. When using this product avoid contact with the eyes. Stop us is no improvement within 4 weeks. Keep out of reach of children. If swallowed, get medical help or ections: Wash the affected area and dry thoroughly. Apply a thin layer of the product over affected ar d by a doctor. Supervise children in the use of this product. For athlete's foot: Pay special attentio , ventilated shoes, and change shoes and socks at least once daily. Use daily for 4 weeks. If condition not effective on the scalp or nails. Inactive Ingredients: Cetyl alcohol, Glycerin, Polyethylene gi glycol, Sodium bisulfite, Sodium laureth sulfate, Water, Zinc stearate. TED BY Tolsho Pharmaceutical California, Inc. 3528 Torrance Blvd, Suite # 320 Torrance, CA 90503 U.S./ MEXICO | nal use only. Do not use on o e and ask a doctor if irritation contact a Poison Control Cent rea twice daily (morning and n on to spaces between the toe persists longer, consult a doct lycol 500, Polyethylene glyco | children noccurs ter right night) or s; wear tor. This ol 4000, ie c c c c c c c c c c c c c c c c c c |

| | 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. | 5 |
| | 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, | Lot. No.: Expiration Date: |
| | and change shoes and socks at least once daily. | <u>ک</u> ۲ |
| | 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, | 30542-V4 |
| | Propylene glycol, Sodium bisulfite, Sodium laureth sulfate, Water, Zinc stearate. | 305 |
| | DISTRIBUTED BY Taisho Pharmaceutical California Inc. 3528 Torrance Blvd, Suite #320 Torrance, CA 90503 U.S.A. MADE IN MEXICO | |
| | | |
| | | |
| | | |
| | FOR THE TREATMENT OF ATHLETE'S FOOT | |
| | | |
| | NET_WT. 1.76_OZ_(50_g) | |
| | | |
| | Drug Facts | |
| | Active ingredients Purpose Undecylenic acid 5% Antifungal | |
| | Zinc undecylenate 18% Antifungal | |
| _ | Use For the treatment of athlete's foot. | |
| | بالوق والالالا المتحد وقال المتحد والمتحد والمتحد والمتحد والمتع | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | UNDECYLENIC ACID . ZINC UNDECYLENATE | 8 |
| | UNDECYLENIC ACID . ZINC UNDECYLENATE | N |
| | UNDECYLENIC ACID . ZINC UNDECYLENATE | |
| | UNDECYLENIC ACID . ZINC UNDECYLENATE | |
| | UNDECYLENIC ACID . ZINC UNDECYLENATE | 30109-V3 |
| | UNDECYLENIC ACID . ZINC UNDECYLENATE | 30109-V3 |
| | UNDECYLENIC ACID . ZINC UNDECYLENATE | 30109-V3 |
| This | UNDECYLENIC ACID . ZINC UNDECYLENATE | |
| Activ | UNDECYLENIC ACID. ZINC UNDECYLENATE FOR THE TREATMENT OF ATHLETE'S FOOT NET WT. 1.76 OZ (50 g) | ermation. |
| Active under | UNDECYLENIC ACID. ZINC UNDECYLENATE FOR THE TREATMENT OF ATHLETE'S FOOT NET WT. 1.76 OZ (50 g) | rmation. children on occurs |
| Active under or if th away. | UNDECYLENIC ACID. ZINC UNDECYLENATE FOR THE TREATMENT OF ATHLETE'S FOOT NET WT. 1.76 OZ (50 g) | ormation. Children on occurs nter right night) or |
| Active under or if th away. as dir well-fi | UNDECYLENIC ACID. ZINC UNDECYLENATE FOR THE TREATMENT OF ATHLETE'S FOOT NET WT. 1.76 OZ (50 g) | ormation. I children In occurs Inter right night) or es; wear ctor. This |
| Active under or if th away. as dir well-fi produ | UNDECYLENIC ACID. ZINC UNDECYLENATE FOR THE TREATMENT OF ATHLETE'S FOOT NET WT. 1.76 OZ (50 g) with its packaged in an outer container and is not labeled for retail sale. Please see outer container for complete drug facts infor the ingredients: Undecylenic acid 5%, Zinc undecylenate 18%. Purpose: Antifungal. Warnings: For external use only. Do not use on to 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 here is no improvement within 4 weeks. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Ce. Directions: Wash the affected area and dry thoroughly. Apply a thin layer of the product over affected area twice daily (morning and thing, ventilated shoes, and change shoes and socks at least once daily. Use daily for 4 weeks. If condition persists longer, consult a dout to this not effective on the scalp or nails. Inactive Ingredients: Cetyl alcohol, Glycerin, Polyethylene glycol 500, Polyethylene glycol to the scale of the | ormation. I children In occurs Inter right night) or es; wear ctor. This |
| Active under or if th away. as dir well-fi produ Propy TO RI | UNDECYLENIC ACID. ZINC UNDECYLENATE FOR THE TREATMENT OF ATHLETE'S FOOT NET WT. 1.76 OZ (50 g) | ormation. a children on occurs nter right night) or es; wear ctor. This col 4000, ä |
| Active under or if th away. as dir well-fi produ Propy TO RI Manu | UNDECYLENIC ACID. ZINC UNDECYLENATE FOR THE TREATMENT OF ATHLETE'S FOOT NET WT. 1.76 OZ (50 g) | ormation. I children In occurs Inter right night) or es; wear ctor. This |

DERMAN ANTIFUNGAL

| Product Informat | tion | | | | | | |
|--|--|---|--|---------------------------------------|--------------------------------|----------|---------------|
| Product Type | | | NDC:54312-125 | | | | |
| Route of Administra | | | | | | | |
| Route of Administra | uon | IOFICAL | | | | | |
| Active Ingredient | t/Active Moie | ety | | | | | |
| | Ing | gredient Name | | | Basis of S | trength | Strength |
| UNDECYLENIC ACID (UNII: K3D86KJ24N) (UNDECYLENIC | | | CID - UNII:K | 3D86KJ24N) | D86KJ24N) UNDECYLENIC ACID 5 g | | |
| ZINC UNDECYLENAT | Έ (UNΙΙ: 388VZ2) | 5DUR) (UNDECYLENIC | C ACID - UNII | :K3D86KJ24N) | ZINC UNDEC | YLENATE | 18 g in 100 g |
| Inactive Ingredie | nts | | | | | | |
| | | Ingredient Nan | ne | | | S | trength |
| CETYL ALCOHOL (U | INII: 936JST6JCN | 1) | | | | | |
| GLYCERIN (UNII: PDC | 6A3C0OX) | | | | | | |
| POLYETHYLENE GLY | YCOL 500 (UNII | : 761NX2Q08Y) | | | | | |
| POLYETHYLENE GLY | YCOL 4000 (UN | II: 4R4HFI6D95) | | | | | |
| PROPYLENE GLYCO | | | | | | | |
| SODIUM BISULFITE (| | | | | | | |
| CODILIM LAUDETLICI | III FATE (IINII) F | | | | | | |
| | | 3PV390UAP0) | | | | | |
| WATER (UNII: 059QF0 | KO0R) | | | | | | |
| WATER (UNII: 059QF0 | KO0R) | | | | | | |
| WATER (UNII: 059QF0 ZINC STEARATE (UNI |)KO0R) II: H92E6QA4FV) | | | | | | |
| WATER (UNII: 059QF0 ZINC STEARATE (UNI Product Characte |)KO0R) II: H92E6QA4FV) | | Score | | | | |
| WATER (UNII: 059QF0 ZINC STEARATE (UNI Product Characte Color |)KO0R) II: H92E6QA4FV) | | Score Size | | | | |
| WATER (UNII: 059QF0 ZINC STEARATE (UNI Product Characte Color Shape |)KO0R) II: H92E6QA4FV) | | | de | | | |
| WATER (UNII: 059QF0 ZINC STEARATE (UNI Product Characte Color Shape Flavor |)KO0R) II: H92E6QA4FV) | | Size | de | | | |
| WATER (UNII: 059QF0 ZINC STEARATE (UNI Product Characte Color Shape Flavor Contains |)KO0R) II: H92E6QA4FV) | | Size | de | | | |
| WATER (UNII: 059QF0 ZINC STEARATE (UNI Product Characte Color Shape Flavor Contains Packaging |)KOOR) II: H92E6QA4FV) eristics | | Size Imprint Co | de Marketing | Start Date | Marketin | ng End Date |
| WATER (UNII: 059QF0 ZINC STEARATE (UNI Product Characte Color Shape Flavor Contains Packaging I tem Code |)KOOR) II: H92E6QA4FV) eristics | white | Size Imprint Co | | Start Date | Marketin | ng End Date |
| WATER (UNII: 059QF0 ZINC STEARATE (UNI Product Characte Color Shape Flavor Contains Packaging I tem Code 1 NDC:54312-125-01 | 0K00R) II: H92E6QA4FV) eristics P 1 in 1 CARTON | white | Size Imprint Co | Marketing | Start Date | Marketin | ng End Date |
| WATER (UNII: 059QF0 ZINC STEARATE (UNI Product Characte Color Shape Flavor Contains Packaging I tem Code 1 NDC:54312-125-01 | 0K00R) II: H92E6QA4FV) eristics P 1 in 1 CARTON | white Package Description | Size Imprint Co | Marketing | Start Date | Marketin | ng End Date |
| WATER (UNII: 059QF0 ZINC STEARATE (UNI Product Characte Color Shape Flavor Contains | DKOOR) II: H92E6QA4FV) eristics I in 1 CARTON 25 g in 1 TUBE; 1 in 1 CARTON | white Package Description | Size Imprint Co I | Marketing 08/12/2013 | Start Date | Marketii | ng End Date |
| WATER (UNII: 059QF0 ZINC STEARATE (UNI Product Characte Color Shape Flavor Contains Packaging I tem Code NDC:54312-125-01 NDC:54312-125-02 NDC:54312-125-02 | 0K00R) II: H92E6QA4FV) eristics P 1 in 1 CARTON 25 g in 1 TUBE; 1 in 1 CARTON 50 g in 1 TUBE; | white P ackage Descriptior Type 0: Not a Combina | Size Imprint Co I | Marketing 08/12/2013 | Start Date | Marketin | ng End Date |
| SODIUM LAURETH SI WATER (UNII: 059QF0 ZINC STEARATE (UNI Product Characte Color Shape Flavor Contains Packaging # Item Code 1 NDC:54312-125-01 1 2 NDC:54312-125-02 2 2 | 0K00R) II: H92E6QA4FV) eristics P 1 in 1 CARTON 25 g in 1 TUBE; 1 in 1 CARTON 50 g in 1 TUBE; | white P ackage Descriptior Type 0: Not a Combina | Size Imprint Co tion Product tion Product | Marketing 08/12/2013 08/12/2013 | Start Date | | ng End Date |

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

Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---------|-----------|----------------------------|
| 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.