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

DERMAN ANTIFUNGAL POWDER

Drug Facts

Active ingredients

Undecylenic acid 2%

Zinc undecylenate 20%

Purpose

Antifungal

Uses

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

Warnings

For external use only.

Do not use

on children under 12 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,

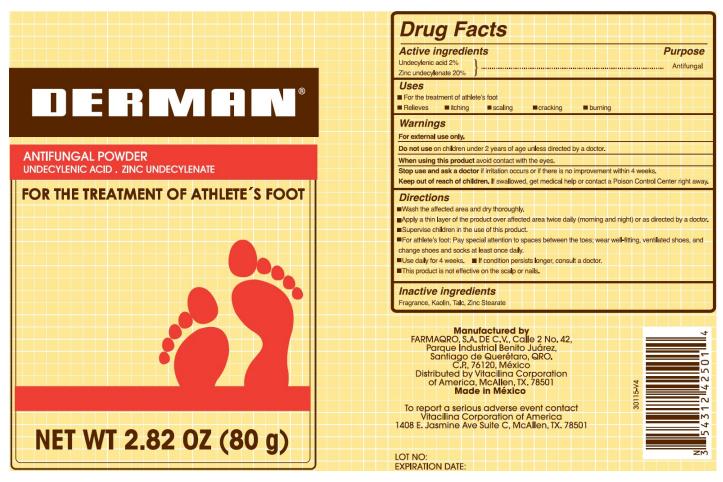
ventilated shoes, and change shoes and socks at least once daily.

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

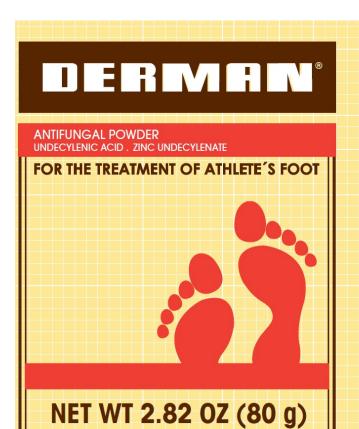
Inactive ingredients

Fragrance, Koalin, Talc, Zinc Stearate

Package Labeling:



Derman Antifungal Powder, 80g (54312-925-01)



Drug Facts

Active ingredients

Undecvlenic acid 2% Zinc undecvlenate 20% Purpose

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

■ cracking

■ burning

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.

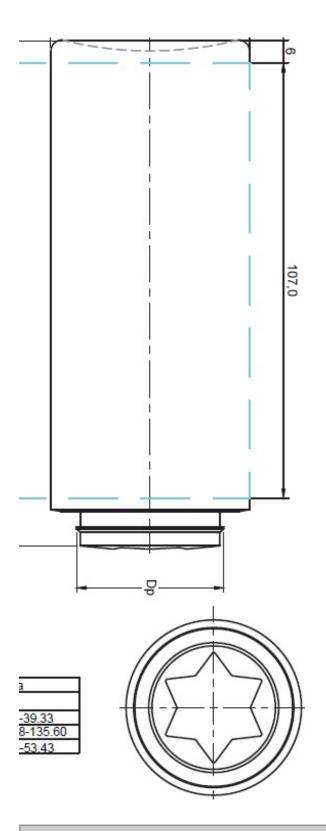
Inactive ingredients

Fragrance, Kaolin, Talc, Zinc Stearate

Manufactured by FARMAQRO, S.A. DE C.V., Calle 2 No. 42, Parque Industrial Benilo Juárez, Santiago de Querélaro, QRO. C.P., 76120, México Distributed by Taisho Pharmaceutical California, Inc. Made In México

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

EXPIRATION DATE:



DERMAN ANTIFUNGAL

zinc undecylenate, undecylenic acid powder

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54312-925	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
UNDECYLENIC ACID (UNII: K3D86KJ24N) (UNDECYLENIC ACID - UNII:K3D86KJ24N)	UNDECYLENIC ACID	2 g in 100 g	
ZINC UNDECYLENATE (UNII: 388VZ 25DUR) (UNDECYLENIC ACID - UNII: K3D86KJ24N)	ZINC UNDECYLENATE	20 g in 100 g	

Inactive Ingredients			
Ingredient Name	Strength		
KAOLIN (UNII: 24H4NWX5CO)			
TALC (UNII: 7SEV7J4R1U)			
ZINC STEARATE (UNII: H92E6QA4FV)			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:54312-925- 01	1 in 1 PACKAGE	12/26/2017		
1		80 g in 1 BOTTLE; 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	09/30/2013		

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

Revised: 10/2023 Compania Internacional de Comercio, S.A.P.I. de C.V.