ZEASORB AF- miconazole nitrate powder Physicians Total Care, Inc.

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.

Drug Facts

Active ingredient

Miconazole nitrate 2%

Purpose

antifungal

Use (Athlete's Foot)

for the cure of most athlete's foot

Warnings

For external use only

Do not use

• on children under 2 years of age unless directed by a doctor.

Avoid contact with the eyes.

Stop use and ask a doctor if (Athlete's Foot)

• irritation occurs or 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 (Athlete's Foot)

- Clean 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.
- 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.

Other information

Product settles during shipment. Package contains full net weight.

Inactive ingredients

acrylamide/sodium acrylate copolymer, aldioxa, chloroxylenol, fragrance, imidurea, microporous cellulose, talc. Contains no starch.

Questions?

call 1-888-438-7426. Side effects should be reported to this number.

Manufactured for: Stiefel Laboratories, Inc. Research Triangle Park, NC 27709

www.zeasorb.com

 $IRONMAN^{\circledR} \ is \ a \ registered \ trademark \ of \ World \ Triathlon \ Corporation \ used \ herein \ by \ permission.$

ZEASORB is a registered trademark of Stiefel Laboratories, Inc.

Additional barcode labeling by:

Physicians Total Care, inc. Tulsa, Oklahoma 74146

Principal Display Panel

NDC 54868-5876-0



Zeasorb®

ANTIFUNGAL TREATMENT

Miconazole Nitrate 2%

Super Absorbent Powder

cures most

athlete's foot

Relieves:

- Itching
- Burning
- Scaling

Official Partner IRONMAN®

Net Wt. 2.5 Oz (71g)

miconazole nitrate powder

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54868-5876(NDC:0145-1506)	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
MICO NAZO LE NITRATE (UNII: VW4H1CYW1K) (MICONAZO LE - UNII:7NNO 0 D7S5M)	MICONAZOLE NITRATE	20.6 mg in 1 g		

Inactive Ingredients				
Ingredient Name	Strength			
ACRYLAMIDE (UNII: 20 R0 35KLCI)				
ALDIO XA (UNII: 8T66I31YNK)				
CHLOROXYLENOL (UNII: 0F32U78 V2Q)				
IMIDUREA (UNII: M629807ATL)				
PO WDERED CELLULO SE (UNII: SMD1X3XO9 M)				
TALC (UNII: 7SEV7J4R1U)				

Product Characteristics			
Color	WHITE (white to off-white)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

F	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54868-5876-0	71 g in 1 BOTTLE		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part333C	03/31/2008		

Labeler - Physicians Total Care, Inc. (194123980)

Establishment				
Name	Address	ID/FEI	Business Operations	
Physicians Total Care, Inc.		194123980	relabel	

Revised: 5/2012 Physicians Total Care, Inc.