

MICONAZOLE NITRATE- anti-fungal powder miconazole nitrate powder

Topco Associates LLC

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.

Anti - Fungal Powder

Active ingredient

Miconazole nitrate 2%

Purpose

Antifungal

Uses

for the cure of most athlete's foot, jock itch and ringworm

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 and ask a doctor if

irritation occurs or there is no improvement within 4 weeks for athlete's foot and ringworm, or 2 weeks for jock itch.

Keep out of reach of children.

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

Directions

- clean the affected area and dry thoroughly
- apply a thin layer of 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
- for athlete's foot and ringworm, use daily for 4 weeks; for jock itch, use daily for 2 weeks
- if conditions persist longer, consult a doctor
- this product is not effective on the scalp or nails

Other Information

- store between 59° - 86°F
- lightly shake bottle to loosen settled powder

Inactive ingredients

aldioxa, chloroxylenol, fragrance, imidurea, powdered cellulose, talc

Questions?

Call 1-888-423-0139

Principal Display Panel

TopCare

ANTIFUNGAL POWDER

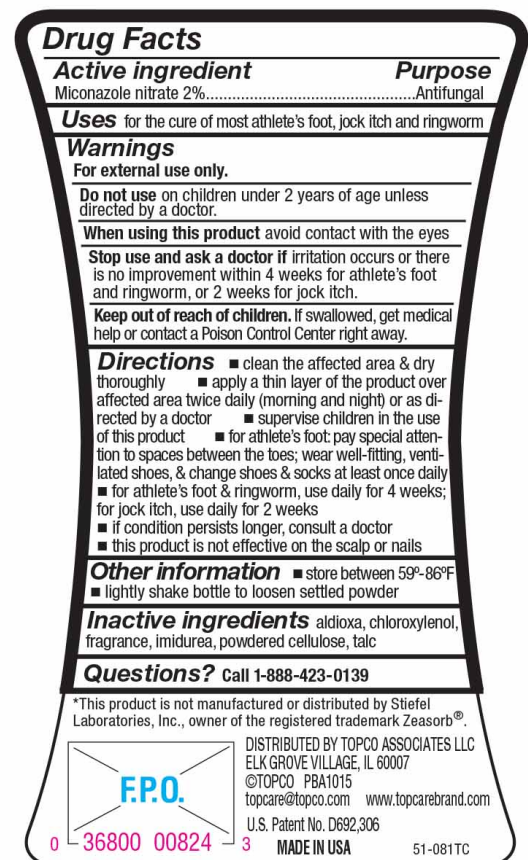
MiconasorbAF

Miconazole Nitrate 2%

- Cures and soothes most athlete's foot, jock itch & ringworm
- Relieves chafing, itching, burning & scaling
- Absorbs moisture

COMPARE TO ZEASORB active ingredients

NET WT 2.5 OZ (71g)



MICONAZOLE NITRATE

anti-fungal powder miconazole nitrate powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-071
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MICONAZOLE NITRATE (UNII: VW4HICYW1K) (MICONAZOLE - UNII:7NNO0D7S5M)	MICONAZOLE NITRATE	1.42 g in 71 g

Inactive Ingredients

Ingredient Name	Strength
ALDIO XA (UNII: 8T66B1YNK)	
CHLOROXYLENOL (UNII: 0F32U78V2Q)	
IMIDUREA (UNII: M629807ATL)	
POWDERED CELLULOSE (UNII: SMD1X3XO9M)	
TALC (UNII: 7SEV7J4R1U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-071-25	71 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/01/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	04/01/2016	

Labeler - Topco Associates LLC (006935977)

Revised: 1/2016

Topco Associates LLC