

## **DESENEX- miconazole nitrate powder**

### **Crown Laboratories**

*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.*

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### **Desenex**

#### ***Active ingredient***

Miconazole nitrate 2%

#### ***Purpose***

Antifungal

#### ***Uses***

- cures most athlete's foot (tinea pedis)
- relieves itching, burning, cracking, and discomfort associated with athlete's foot

#### ***Warnings***

**For external use only · Avoid contact with eyes.**

#### **Do Not Use**

- for nail or scalp infections

#### **When using this product**

- do not get into the eyes

#### **Stop use and ask a doctor if**

- irritation occurs or gets worse
- 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***

- adults and children 2 years and older
- wash the affected area with soap and water and dry thoroughly before applying
- apply a thin layer over affected area twice a day (morning and night) or as directed by a doctor
- supervise children in the use of this product

- pay special attention to the spaces between the toes. Wear well-fitting, ventilated shoes and change shoes and socks at least once a day.
- use every day for 4 weeks
- children under 2 years of age: ask a doctor

***Other information***

- Store at 20 ° - 25 °C (68 ° - 77 °F) [see USP Controlled Room Temperature].
- See container bottom for lot number and expiration date

***Inactive ingredients***

Aldioxa, Chloroxyleneol, Croscarmellose Sodium, Fragrance, Imidazolidinyl Urea, Magnesium Stearate, Microcrystalline Cellulose, Sodium Acrylates Crosspolymer-2

***Questions or comments?***

call **1-833-279-6522**

**Principal Display**

NDC 0316-0225-30

New & Improved

Desenex®

Miconazole Nitrate 2% Antifungal Treatment

PRESCRIPTION STRENGTH

TRIPLE ACTION POWDER

Absorbs Wetness

Repels Moisture

Relieves Itching & Burning

Cures Most Athlete's Foot

NET WT. 3 oz (85 g)

PRODUCT PACKAGED BY WEIGHT NOT VOLUME

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Distributed by: **Crown Laboratories, Inc.** Johnson City, TN 37604

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P11528.01

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Made in USA

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## Drug Facts

<b>Active ingredient</b>	<b>Purpose</b>
Miconazole nitrate 2%	Antifungal

<b>Uses</b>
<ul style="list-style-type: none"> <li>• cures most athlete's foot (tinea pedis)</li> <li>• relieves itching, burning, cracking, and discomfort associated with athlete's foot.</li> </ul>

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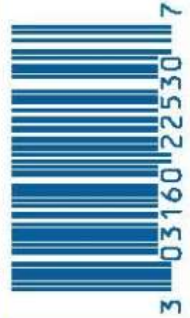
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<b>Inactive ingredients</b>
Aldioxa, Chloroxylenol, Croscarmellose Sodium, Fragrance, Imidazolidinyl Urea, Magnesium Stearate, Microcrystalline Cellulose, Sodium Acrylates Crosspolymer-2

<b>Questions or comments?</b>
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## DESENEX

miconazole nitrate powder

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0316-0225
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>MICONAZOLE NITRATE</b> (UNII: VV4H1CYW1K) (MICONAZOLE - UNII: 7NNO0D7S5M)	MICONAZOLE NITRATE	20 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>CHLOROXYLENOL</b> (UNII: 0F32U78V2Q)	
<b>IMIDUREA</b> (UNII: M629807ATL)	
<b>ALDIOXA</b> (UNII: 8T66I31YNK)	
<b>SODIUM ACRYLATES CROSSPOLYMER-2</b> (UNII: D3HPR4WW6F)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0316-0225-15	43 g in 1 CONTAINER; Type 0: Not a Combination Product	12/01/2018	
2	NDC:0316-0225-30	85 g in 1 CONTAINER; Type 0: Not a Combination Product	12/01/2018	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	08/03/2009	

**Labeler** - Crown Laboratories (079035945)

Revised: 2/2022

Crown Laboratories