

**MICONAZOLE NITRATE- miconazole nitrate cream
FRED'S, INC.**

Miconazole Nitrate

Drug Facts

Active ingredient

Miconazole Nitrate USP 2% (100 mg in each applicatorful)

Purpose

Vaginal antifungal

Uses

- treats vaginal yeast infections
- relieves external itching and irritation due to a vaginal yeast infection

Warnings

For vaginal use only

Do not use if you have never had a vaginal yeast infection diagnosed by a doctor

Ask a doctor before use if you have

- **vaginal itching and discomfort for the first time**
- **lower abdominal, back or shoulder pain, fever, chills, nausea, vomiting, or foul-smelling vaginal discharge. You may have a more serious condition.**
- vaginal yeast infections often (such as once a month or 3 in 6 months). You could be pregnant or have a serious underlying medical cause for your symptoms, including diabetes or a weakened immune system.
- been exposed to the human immunodeficiency virus (HIV) that causes AIDS

Ask a doctor or pharmacist before use if you are taking the prescription blood thinning medicine warfarin, because bleeding or bruising may occur

When using this product

- do not use tampons, douches, spermicides, or other vaginal products. Condoms and diaphragms may be damaged and fail to prevent pregnancy or sexually transmitted diseases (STDs)
- do not have vaginal intercourse
- mild increase in vaginal burning, itching or irritation may occur
- if you do not get complete relief ask a doctor before using another product

Stop use and ask a doctor if

- **symptoms do not get better in 3 days**
- **symptoms last more than 7 days**
- **you get a rash or hives, abdominal pain, fever, chills, nausea, vomiting or foul-smelling vaginal discharge**

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- before using this product, read the enclosed consumer information leaflet for complete directions and information
- adults and children 12 years of age and over:
 - **applicators:** insert 1 applicatorful into the vagina at bedtime for 7 nights in a row. Throw away applicator after each use.
 - use the same tube of cream if you have itching and irritation on the skin outside the vagina. Squeeze a small amount of cream onto your fingertip. Apply to itchy, irritated skin outside the vagina (vulva). Use 2 times daily for up to 7 days as needed.
- children under 12 years of age: ask a doctor

Other information

- do not purchase if carton is opened
- do not use if seal over tube opening has been punctured or is not visible
 - To open:** unscrew cap, use pointed end on cap to puncture seal
 - To close:** screw cap back onto the tube
- store at 20°-25°C (68°-77°F)
- see carton or tube crimp for lot number and expiration date

Inactive ingredients

Apricot Kernel Oil/PEG-6, Butylated Hydroxytoluene, Mineral Oil, PEG-6-32 Stearate/Glycol Stearate, Purified Water and Benzoic Acid (0.20%) as a preservative

Questions?

Call 1-866-923-4914

DISTRIBUTED BY: fred's, Inc.
4300 NEW GETWELL RD,
MEMPHIS, TN 38118

PRINCIPAL DISPLAY PANEL - 45 g Tube Carton

fred's
Pharmacy

Cures Most Vaginal
Yeast Infections

7 Day
Treatment

7 DAY VAGINAL CREAM
Miconazole Nitrate Vaginal Cream USP (2%)
(Miconazole Nitrate 100 mg per application)

VAGINAL ANTIFUNGAL

Educational Brochure Enclosed

One 45 g (1.5 oz) Tube Of Miconazole Nitrate Vaginal Cream USP (2%) & 7 Disposable Applicators



NDC55315-815-63

Compare to the Active Ingredient in Montistat® 7*

7 DAY VAGINAL CREAM

Miconazole Nitrate Vaginal Cream USP (2%)
(Miconazole Nitrate 100 mg per application)

VAGINAL ANTIFUNGAL



Cures Most Vaginal Yeast Infections



7 Day Treatment

Antifungal Cream & 7 Disposable Applicators

7 DAY VAGINAL CREAM

Miconazole Nitrate Vaginal Cream USP (2%) (Miconazole Nitrate 100 mg per application)

VAGINAL ANTIFUNGAL

7 Day Treatment

Cures Most Vaginal Yeast Infections



Cures Most Vaginal Yeast Infections

7 Day Treatment

7 DAY VAGINAL CREAM

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SKU365653



*All trademarks are property of their respective owners. This product is not affiliated with the makers/owners of Montistat® 7.

DISTRIBUTED BY: fred's, Inc.
4300 NEW GETWELL RD,
MEMPHIS, TN 38118
www.fredsinc.com

100% satisfaction guaranteed

Questions or comments:
1-855-331-FRED (3733)

Made in Canada

Questions? Call 1-866-92-3-414

Inactive ingredients: Apricot Kernel Oil, Polyethylene Glycol, Polyethylene Glycol, Stearate, Glycerol Stearate, Purified Water and Benzoic Acid (0.2%) as a preservative

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Cures Most Vaginal Yeast Infections

7 Day Treatment

Drug Facts (continued)

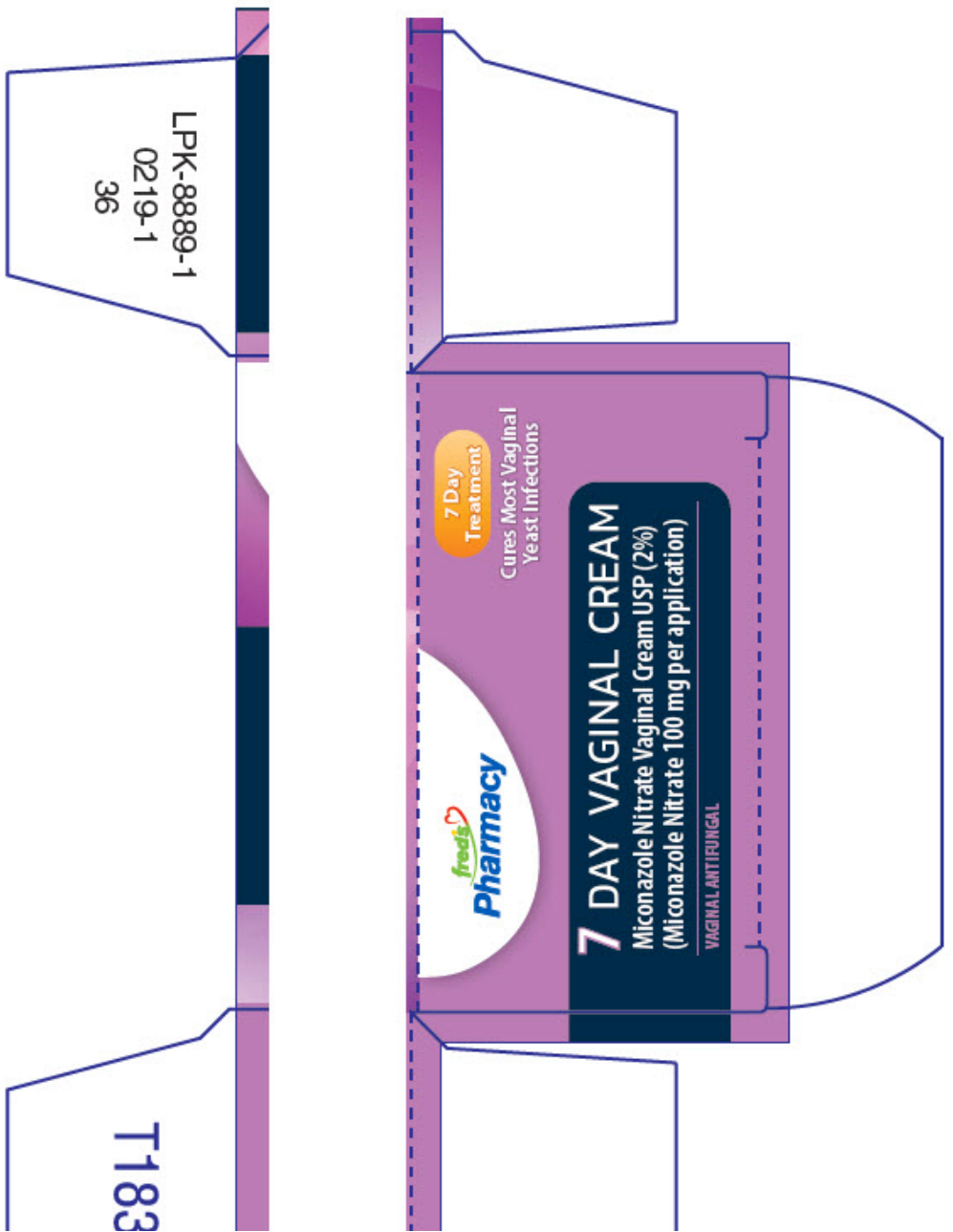
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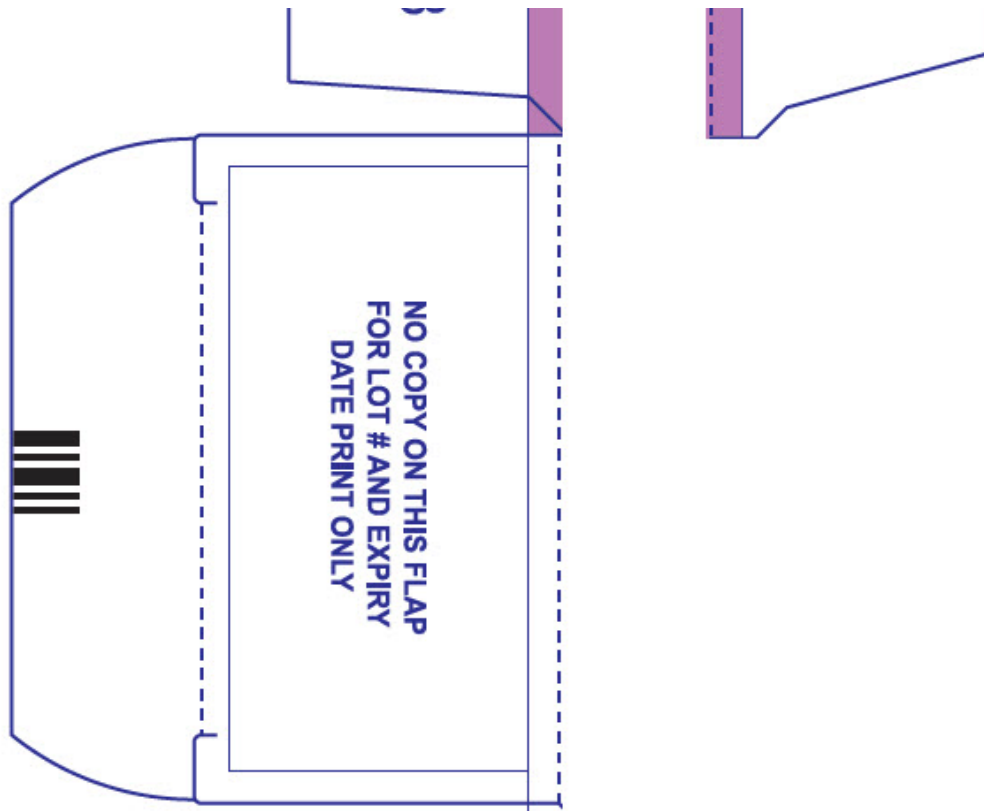
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MICONAZOLE NITRATE

miconazole nitrate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55315-815
Route of Administration	VAGINAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Miconazole Nitrate (UNII: VW4HICYW1K) (Miconazole - UNII:7NNO0D7S5M)	Miconazole Nitrate	20 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
Butylated Hydroxytoluene (UNII: 1P9D0Z171K)	
Mineral Oil (UNII: T5L8T28FGP)	
Water (UNII: 059QF0KO0R)	
Benzoic Acid (UNII: 8SKN0B0MIM)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55315-815-	15.1 CARTON	02/11/2010	

1	63	1 UNIT CARTON	02/14/2015	
1		45 g in 1 TUBE, WITH APPLICATOR; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
ANDA	ANDA074444		01/13/1997	

Labeler - FRED'S, INC. (005866116)

Revised: 2/2019

FRED'S, INC.