

7 DAY VAGINAL - miconazole nitrate cream

Cardinal Health

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% (100 mg in each applicator)

Miconazole nitrate 2% (as external cream)

Purpose

Vaginal antifungal

Uses

- treats repeat vaginal yeast infections
- relieves external itching and irritation due to a repeat 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 medication warfarin, because bleeding or bruising may occur.

When using this product

- do not use tampons, douches, spermicides, or other vaginal products
- do not have vaginal intercourse
- condoms and diaphragms may be damaged and fail to prevent pregnancy or sexually transmitted diseases (STDs)

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 instructions
- adults and children 12 years of age and over:
 - **applicator:** insert one applicatorful into the vagina at bedtime for 7 nights in a row
 - **external cream:** squeeze a small amount of cream onto your fingertip. Gently apply the cream onto the itchy, irritated skin outside the vagina. Use daily for up to 7 days as needed
- children under 12 years of age: ask a doctor

Other information

- do not use if seal over tube opening has been punctured or cannot be seen
- store at room temperature 15°-30°C (59-86°F). Avoid heat over 30°C or 86°F.

Inactive ingredients

benzoic acid, BHA, mineral oil, peglicol 5 oleate, pegoxol 7 stearate, purified water

Questions?

1-800-200-6313

PRINCIPAL DISPLAY PANEL

NDC 37205-590-29

LEADER®

7 DAY VAGINAL CREAM

Miconazole Nitrate VAGINAL CREAM 2% • VAGINAL ANTIFUNGAL

Cures most vaginal yeast infections.

Relieves external vulvar itching and irritation associated with a yeast infection

Compare to Monistat® 7 active ingredient*

NET WT 1.59 OZ (45 g)

SATISFACTION GUARANTEED

**DISTRIBUTED BY
CARDINAL HEALTH
DUBLIN, OH 43017
CIN 1362490**

www.myleader.com
1-800-200-6313

All **Leader**[®] Brand products are 100% satisfaction guaranteed or return to place of purchase for a full refund.

*This product is not manufactured or distributed by Johnson & Johnson, distributor or manufacturer of **MONISTAT**[®] 7. **MONISTAT**[®] 7 is a registered trademark of Johnson & Johnson.

10-25237LR2

Drug Facts (continued)

Warnings
For vaginal use only

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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.
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Drug Facts (continued)

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Inactive ingredients: benzoic acid, BHA, mineral oil, polycol 5 oleoils, polycol 7 stearate, purified water

Questions? 1-800-200-6313

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NDC 37205-590-29

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**Compare to
Monistat[®] 7
active ingredients***

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80% UPC
do not print keyline
0-96295-36249-7

7 DAY VAGINAL
miconazole nitrate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37205-590
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Miconazole Nitrate (UNII: VW4H1CYW1K) (Miconazole - UNII:7NNO0D7S5M)	Miconazole Nitrate	2 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
Benzoic Acid (UNII: 8SKN0B0MIM)	
Butylated Hydroxyanisole (UNII: REK4960K2U)	
Mineral Oil (UNII: T5L8T28FGP)	
Peg-5 Oleate (UNII: 0240V77G50)	
Pegoxol 7 Stearate (UNII: 3EW5AXE5X5)	
Water (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37205-590-29	45 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	03/16/2009	

Labeler - Cardinal Health (097537435)**Registrant** - G & W Laboratories, Inc. (001271188)**Establishment**

Name	Address	ID/FEI	Business Operations
G & W Laboratories, Inc.		001271188	MANUFACTURE(37205-590)

Revised: 1/2011

Cardinal Health