

**MICONAZOLE 3 COMBINATION PACK- miconazole nitrate
Cardinal Health (Leader) 70000**

Miconazole 3 Combination Pack

Drug Facts

Active ingredients

Miconazole nitrate, USP 200 mg (in each suppository)
Miconazole nitrate, USP 2% (external cream)

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 and 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.

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 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 - 1 Applicator Carton

- before using this product read the enclosed consumer information leaflet for complete directions and information
- **adults and children 12 years of age and over:**
 - **suppositories:** insert 1 suppository into the vagina at bedtime for 3 nights in a row. Wash applicator after each use.
 - **external cream:** Use cap to puncture seal. Squeeze a small amount of cream onto your fingertip. Apply the cream onto the itchy, irritated skin outside the vagina. Use 2 times daily for up to 7 days, as needed.
- **children under 12 years of age: ask a doctor**

Directions - 3 Applicator Carton

- before using this product read the enclosed consumer information leaflet for complete directions and information
- **adults and children 12 years of age and over:**
 - **suppositories:** insert 1 suppository into the vagina at bedtime for 3 nights in a row. Throw applicator away after use.
 - **external cream:** Use cap to puncture seal. Squeeze a small amount of cream onto your fingertip. Apply the cream onto the itchy, irritated skin outside the vagina. Use 2 times daily for up to 7 days, as needed.
- **children under 12 years of age: ask a doctor**

Other information

- do not use if suppository wrapper is missing or damaged (each suppository is individually wrapped)
- do not use if seal over tube opening has been punctured or is not visible
- do not purchase if carton is open
- store at 20°-25°C (68°-77°F) [see USP Controlled Room Temperature] excursions permitted to 15°-30°C (59°-86°F).

Inactive ingredients

- suppository: hydrogenated vegetable oil
- external cream: benzoic acid, butylated hydroxyanisole, mineral oil, oleoyl polyoxylglycerides, pegoxol 7 stearate, purified water

Questions?

1-888-838-2872 between 9 am and 5 pm ET, Monday-Friday.

Principal Display Panel

LEADER™

NDC 70000-0025-1

Miconazole 3
Combination Pack
Miconazole Nitrate Vaginal Suppositories, USP 200 MG
and Miconazole Nitrate Vaginal Cream, USP 2%
Vaginal Antifungal

Cures Most Vaginal Yeast Infections
Relieves Associated External Itching and Irritation

COMPARE TO MONISTAT[®] 3 active ingredient*
100% Money Back Guarantee

3 Miconazole Nitrate Vaginal Suppositories, USP 200 mg Plus
1 Tube of Miconazole Nitrate Vaginal Cream, USP 2% - NET WT 0.32 OZ (9 g)

3 Day Treatment

3 Vaginal Suppositories with Reusable Applicator
Plus External Cream for Itch Relief

LEADERTM

Miconazole 3 Combination Pack

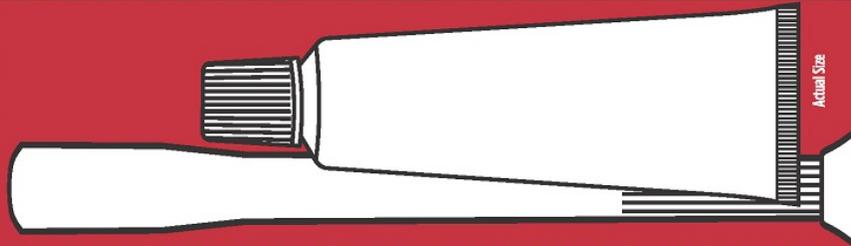


3 Day Treatment

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Actual Size

LEADERTM

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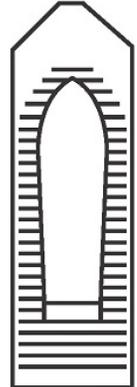
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3 SUPPOSITORIES



Actual Size

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1-800-200-6355

Essential to CareSM since 1979



All LEADERTM Brand Products Have A
100% Money Back Guarantee

Return to place of purchase if not satisfied.

CIN 5520432 REV. 5/19



Ask a doctor or pharmacist before use If you are taking the prescription blood thinning medicine, warfarin, because bleeding and 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).
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Stop use and ask a doctor if

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- you get a rash or hives, abdominal pain, fever, chills, nausea, vomiting, or foul-smelling 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:
 - external cream: Use cap to puncture seal. Squeeze a small amount of cream onto your fingertip. Apply the cream onto the vagina. Insert 1 suppository into the vagina at bedtime for 3 nights in a row. Wash applicator after each use.
 - suppositories: Insert 2 suppositories into the vagina daily for up to 7 days, as needed.
- children under 12 years of age: ask a doctor

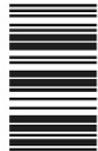
Other information

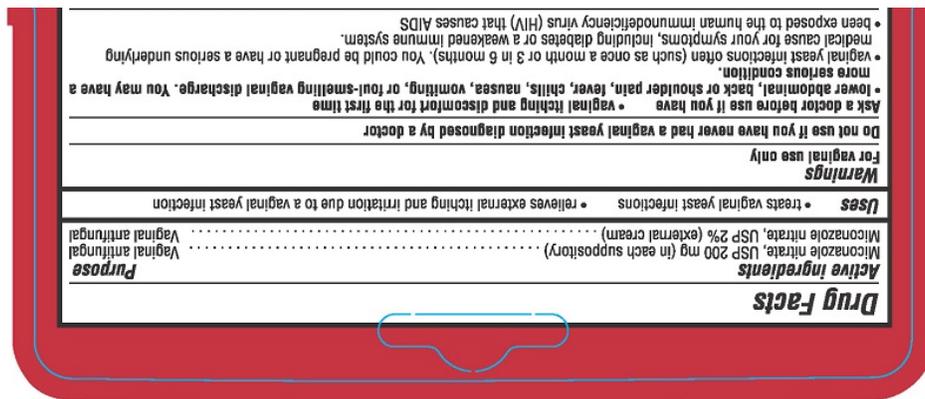
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Inactive ingredients

- external cream: benzoic acid, butylated hydroxyanisole, mineral oil, oleoyl polyoxyglycerides, pegoxol 7 stearate, purified water
- suppository: hydrogenated vegetable oil

Questions? 1-888-838-2872 between 9 am and 5 pm ET, Monday-Friday.





Principal Display Panel

LEADER™

NDC 70000-0025-2

Miconazole 3
 Combination Pack
 Miconazole Nitrate Vaginal Suppositories, USP 200 MG
 and Miconazole Nitrate Vaginal Cream, USP 2%
 Vaginal Antifungal

Cures Most Vaginal Yeast Infections
 Relieves Associated External Itching and Irritation

COMPARE TO MONISTAT® 3 active ingredient*
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3 Miconazole Nitrate Vaginal Suppositories, USP 200 mg Plus
 1 Tube of Miconazole Nitrate Vaginal Cream, USP 2% - NET WT 0.32 OZ (9 g)

3 Day Treatment

3 Vaginal Suppositories with Disposable Applicators
 Plus External Cream for Itch Relief

LEADERTM

Miconazole 3 Combination Pack

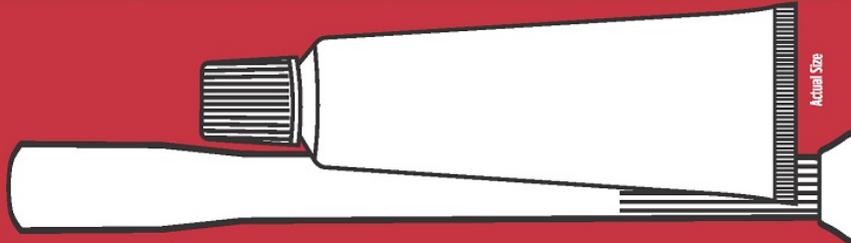


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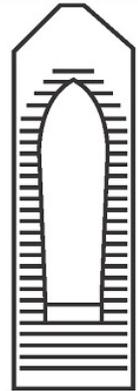
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3 SUPPOSITORIES



Actual Size

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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 discharge

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

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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:**

• **suppositories:** Insert 1 suppository into the vagina at bedtime for 3 nights in a row. Throw applicator away after use.

• **external cream:** Use cap to puncture seal. Squeeze a small amount of cream onto your fingertip. Apply the cream onto the

• **children under 12 years of age:** ask a doctor

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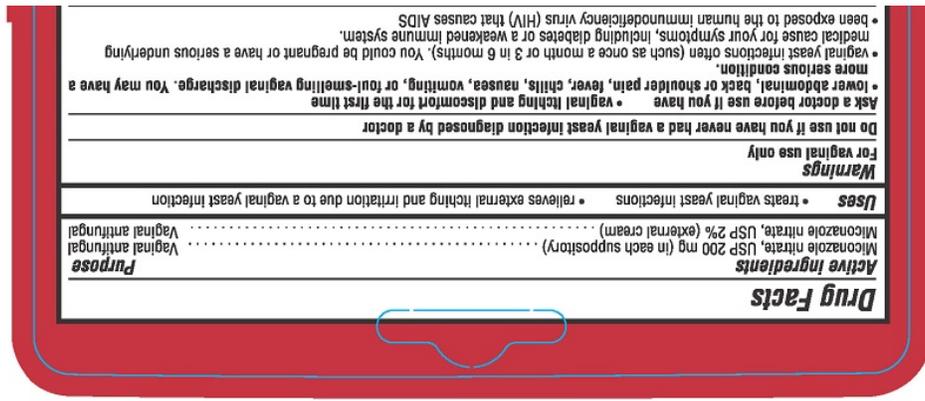
Inactive ingredients

• suppository: hydrogenated vegetable oil

• external cream: benzoic acid, butylated hydroxyanisole, mineral oil, oleoyl polyoxyglycerides, pegoxol 7 stearate, purified water

Questions? 1-888-838-2872 between 9 am and 5 pm ET, Monday-Friday.





MICONAZOLE 3 COMBINATION PACK

miconazole nitrate kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0025
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0025-1	1 in 1 PACKAGE, COMBINATION; Type 0: Not a Combination Product	07/01/2019	
2	NDC:70000-0025-2	1 in 1 PACKAGE, COMBINATION; Type 0: Not a Combination Product	07/01/2019	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BLISTER PACK	3
Part 2	1 TUBE	9 g

Part 1 of 2

MICONAZOLE 3

miconazole nitrate suppository

Product Information

Route of Administration	VAGINAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MICONAZOLE NITRATE (UNII: VW4H1CYW1K) (MICONAZOLE - UNII:7NNO0D7S5M)	MICONAZOLE NITRATE	200 mg

Inactive Ingredients

Ingredient Name	Strength
HYDROGENATED PALM KERNEL OIL (UNII: FM8D1RE2VP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		3 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA074926	07/01/2019	

Part 2 of 2

MICONAZOLE 3

miconazole nitrate cream

Product Information

Route of Administration	VAGINAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MICONAZOLE NITRATE (UNII: VW4H1CYW1K) (MICONAZOLE - UNII:7NNO0D7S5M)	MICONAZOLE NITRATE	10 mg in 0.5 g

Inactive Ingredients

Ingredient Name	Strength
BENZOIC ACID (UNII: 8SKN0B0MIM)	
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
MINERAL OIL (UNII: T5L8T28FGP)	
APRICOT KERNEL OIL PEG-6 ESTERS (UNII: DRG3KJZ1TJ)	
PEGXOL 7 STEARATE (UNII: 3EW5AXE5X5)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		9 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA074926	07/01/2019	

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Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA074926	07/01/2019	

Labeler - Cardinal Health (Leader) 70000 (097537435)

Revised: 9/2019

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