

MICONAZOLE 3 COMBINATION PACK- miconazole nitrate

Major Pharmaceuticals

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

- 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 polyoxyglycerides, pegoxol 7 stearate, purified water

Questions?

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

Principal display panel

Compare to the active ingredient in Monistat® 3*

Miconazole 3

Combination Pack

Miconazole Nitrate Vaginal Suppositories, USP 200 mg

and Miconazole Nitrate Vaginal Cream, USP 2%

200 mg/2%

Vaginal Antifungal

Cures most vaginal yeast infections

Relieves associated external itching and irritation

3 Miconazole Nitrate Vaginal Suppositories, USP 200 mg

with 3 disposable applicators plus 1 tube of

Miconazole Nitrate Vaginal Cream, USP 2%

NET WT. 0.32 OZ (9g) TUBE

*This product is not affiliated with, manufactured by, or produced by the makers or owners of Monistat® 3.

Retain carton for complete information.

Distributed by:

MAJOR® PHARMACEUTICALS

17177 N Laurel Park Drive

Suite 233

Livonia, MI 48152, USA

Package label

MAJOR[®]

NDC 0904-5415-01
Compare to the active
ingredient in Monistat[®] 3*

Miconazole 3 Combination Pack

Miconazole Nitrate Vaginal Suppositories, USP 200 mg
and Miconazole Nitrate Vaginal Cream, USP 2%

200 mg/2%



MAJOR[®]

NDC 0904-5415-01
Compare to the active
ingredient in Monistat[®] 3*

Miconazole 3 Combination Pack

Miconazole Nitrate Vaginal Suppositories, USP 200 mg
and Miconazole Nitrate Vaginal Cream, USP 2%

200 mg/2%

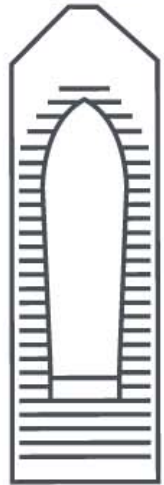
Vaginal Antifungal

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with 3 disposable applicators plus 1 tube of
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NET WT. 0.32 OZ (9g) TUBE

3 Suppositories



Actual Size

Distributed by:
MAJOR[®] PHARMACEUTICALS
17177 N Laurel Park Drive
Suite 233
Livonia, MI 48152, USA

Retain carton for complete information.

PLD-B672A F0007103 VC710320

Rev. 08/20 M-58 Re-order No. 700600



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Questions? Call 1-800-616-2471
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Drug Facts	Active Ingredients Miconazole nitrate, USP 200 mg (in each suppository)..... Miconazole nitrate, USP 2% (external cream)
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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 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 (1-800-222-1222) 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: ■ 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 to itchy, irritated skin outside the vagina. Use 2 times daily for up to 7 days. ■ children under 12 years of age: ask a doctor as needed.
Other Information	■ do not use if seal over tube opening has been punctured or is not visible ■ do not purchase if carton is open

MAJOR Vaginal Antifungal Cream

MICONAZOLE 3 COMBINATION PACK

miconazole nitrate kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0904-5415
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-5415-01	1 in 1 PACKAGE, COMBINATION; Type 0: Not a Combination Product	12/02/2002	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BLISTER PACK	3 in 0
Part 2	1 TUBE	9 g

Part 1 of 2

MICONAZOLE 3

miconazole nitrate suppository

Product Information

Route of Administration VAGINAL

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	12/02/2002	

Part 2 of 2

MICONAZOLE 3

miconazole nitrate cream

Product Information

Route of Administration VAGINAL

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
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BENZOIC ACID (UNII: 8SKN0B0MIM)	
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
MINERAL OIL (UNII: T5L8T28FGP)	
APRICOT KERNEL OIL PEG-6 ESTERS (UNII: DRG3KJZ1TJ)	
PEGOXOL 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		

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ANDA	ANDA074926	12/02/2002	

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ANDA	ANDA074926	12/02/2002	

Labeler - Major Pharmaceuticals (191427277)

Revised: 12/2022

Major Pharmaceuticals