

MICONAZOLE 3 COMBINATION PACK- miconazole nitrate
CVS Pharmacy

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?

Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

Principal display panel

Compare to the active ingredient in Monistat® 3

3-Dat Treatment

M-ZOLE 3

Combination Pack

MICONAZOLE NITRATE VAGINAL SUPPOSITORIES, USP 200 mg and

NICONAZOLE NITRATE VAGINAL CREAM, USP 2%

Vaginal antifungal

Cures most vaginal yeast infections and relieves associated external itching and irritation

NET WT Z (g)

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

Distributed by: CVS Pharmacy, Inc.

One CVS Drive, Woonsocket, RI 02895

Package label

CVSHealth.

Combination Pack

- Cures most vaginal yeast infections
- Relieves associated external itching & irritation

3 Vaginal suppositories with disposable applicators



Plus external cream for Itch relief



3 Applicators



Actual Size

CVSHealth.

NDC 59779-773-43

Compare to the active ingredient in Monistat® 3*

3-Day Treatment

3 Suppositories

M-Zole 3

Combination Pack

MICONAZOLE NITRATE VAGINAL SUPPOSITORIES, USP 200 mg and
MICONAZOLE NITRATE VAGINAL CREAM, USP 2%

Vaginal antifungal

Cures most vaginal yeast infections and relieves associated external itching and irritation

**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)**



Actual Size

Distributed by: **CVS Pharmacy, Inc.**
One CVS Drive, Woonsocket, RI 02895
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CVS.com® 1-800-SHOP CVS
V-36029



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PLD-B672A FC007134 VC710332

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external cream: benzoic acid, butylated hydroxytoluene, mineral oil, oleoyl polyoxyglycerides, pegoxal 7 stearate, purified water

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Vaginal antifungal

Purpose
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Warnings
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■ vaginal itching and discomfort for the first time
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■ 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.
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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
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Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

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Inactive ingredients
suppository: hydrogenated vegetable oil

CVS HEALTH Vaginal antifungal Cream

MICONAZOLE 3 COMBINATION PACK

miconazole nitrate kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59779-773
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59779-773-03	1 in 1 PACKAGE, COMBINATION; Type 0: Not a Combination Product	03/01/2001	12/31/2014
2	NDC:59779-773-43	1 in 1 PACKAGE, COMBINATION; Type 0: Not a Combination Product	03/01/2001	

Quantity of Parts

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

MICONAZOLE 3

miconazole nitrate suppository

Product Information

Route of Administration VAGINAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MICONAZOLE NITRATE (UNII: VV4H1CYW1K) (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	03/01/2001	

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: VV4H1CYW1K) (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)	
PEGOXOL 7 STEARATE (UNII: 3EW5AXE5X5)	
WATER (UNII: 059QF0KO0R)	

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	03/01/2001	

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ANDA	ANDA074926	03/01/2001	

Labeler - CVS Pharmacy (062312574)

Revised: 1/2023

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