

MICONAZOLE 3 COMBINATION PACK- miconazole nitrate
Rite Aid Corporation

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
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

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. Gently 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*

COMBINATION PACK

Miconazole 3

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

VAGINAL ANTIGUNGAL

3 - DAY TREATMENT

Vaginal suppositories with 3 disposable applicators

plus external cream for itch relief

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 OZ (g)

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

DISTRIBUTED BY: RITE AID,

30 HUNTER LANE, CAMP HILL, PA 17011

www.riteaid.com

Package label

NDC 11822-7310-7

Compare to the active ingredient in **Monistat® 3***

COMBINATION PACK Miconazole 3

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

VAGINAL ANTIFUNGAL

3-DAY TREATMENT

Vaginal suppositories with 3 disposable applicators plus external cream for itch relief



COMBINATION PACK Miconazole 3

Miconazole Nitrate Vaginal Suppositories, USP 200 mg & Miconazole Nitrate Vaginal Cream, USP 2%, Vaginal Antifungal

3-DAY TREATMENT

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. (9 g)

3 Suppositories



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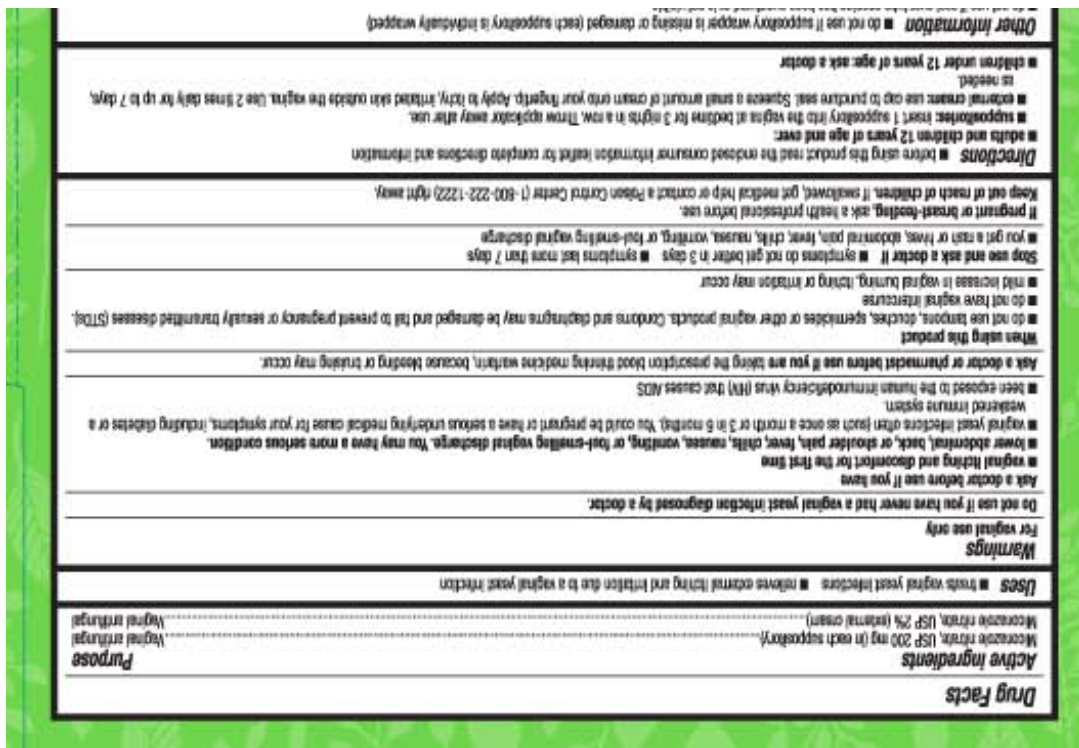
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**SATISFACTION
GUARANTEE**

If you're not satisfied, we'll happily refund your money.



Questions? Call 1-877-732-8239 Monday-Friday 9AM-5PM EST
Active Ingredients
suppository: hydroxyethyl vegetable oil
external cream: benzoic acid, butylated hydroxytoluene, mineral oil, oleoyl polyglycerides, polyol 7 stearate, purified water
■ do not use a seal over the opening and avoid puncture or air intake
■ 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)



RITE AID Vaginal Treatment

MICONAZOLE 3 COMBINATION PACK

miconazole nitrate kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11822-7310
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11822-7310-7	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

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	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: 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)

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	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA074926	03/01/2001	

Labeler - Rite Aid Corporation (014578892)

Revised: 12/2022

Rite Aid Corporation