

**MICONAZOLE 3 COMBINATION PACK- miconazole nitrate
EQUATE (Wal-Mart Stores, Inc.)**

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 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. Wash 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 polyoxylglycerides, pegoxol 7 stearate, purified water

Questions?

1-888-287-1915

Principal Display Panel

*Compare to the active ingredient in Monistat® 3

M-Zole 3

Combination Pack

Vaginal antifungal

Miconazole nitrate vaginal suppositories, USP 200 mg

and Miconazole nitrate vaginal cream, USP 2%

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

3 miconazole nitrate vaginal suppositories, USP 200 mg with 1 reusable applicator 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.

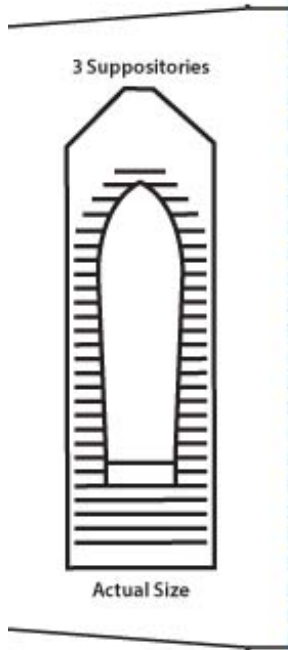
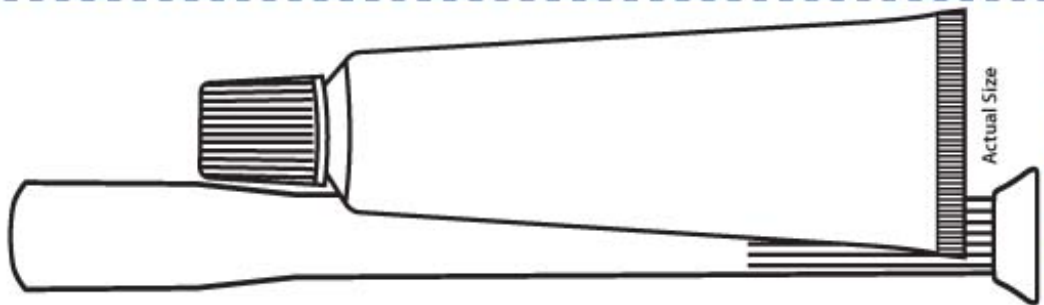
Distributed by:

Wal-Mart Inc

Bentonville AR 72716

Package Label

<p>Drug Facts (continued)</p> <p>■ you get a rash or fever, abdominal pain, fever, chills, nausea, vomiting, or food-empting vaginal discharge</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center (1-800-232-1222) right away.</p> <p>Directions ■ before using this product, read the enclosed consumer information leaflet for complete directions and information</p> <p>■ adults and children 12 years of age and over:</p> <p>■ suppositories: insert 1 suppository into the vagina at bedtime for 3 nights in a row. Wash applicator after each use.</p> <p>■ 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, as needed.</p> <p>■ children under 12 years of age: ask a doctor</p> <p>Other information ■ do not use if suppository wrapper is missing or damaged (each suppository is individually wrapped)</p> <p>■ do not use if seal over this opening has been punctured or is not visible</p> <p>■ do not purchase if carton is open</p> <p>■ store at 20°-25°C (68°-77°F) (see USP Controlled Room Temperature) excursions permitted to 15°-30°C (59°-86°F)</p> <p>Inactive ingredients</p> <p>suppository: hydrogenated vegetable oil, ester gum, benzoic acid, butylated hydroxytoluene, mineral oil, oleoyl polyoxyethylene, polyol, 7 stearyl, purified water</p> <p>Questions? 1-888-287-1915</p>	<p>Drug Facts</p> <p>Active ingredients</p> <p>Miconazole nitrate, USP 200 mg (in each suppository); Vaginal antifungal Miconazole nitrate, USP 2% (external cream); Vaginal antifungal</p> <p>Purpose</p> <p>■ treats vaginal yeast infections</p> <p>■ relieves external itching and irritation due to a vaginal yeast infection</p> <p>Warnings</p> <p>For vaginal use only</p> <p>Do not use if you have never had a vaginal yeast infection diagnosed by a doctor.</p> <p>Ask a doctor before use if you have</p> <p>■ vaginal itching and discomfort for the first time</p> <p>■ lower abdominal, back, or shoulder pain, fever, chills, nausea, vomiting, or food-empting vaginal discharge. You may have a more serious condition.</p> <p>■ 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.</p> <p>■ been exposed to the human immunodeficiency virus (HIV) that causes AIDS</p> <p>Ask a doctor or pharmacist before use if you are taking the prescription blood thinning medicine warfarin, because bleeding or bruising may occur.</p> <p>When using the 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).</p> <p>■ do not have vaginal intercourse</p> <p>■ mild increase in vaginal burning, itching or irritation may occur</p> <p>Stop use and ask a doctor if ■ symptoms do not get better in 5 days</p> <p>■ symptoms last more than 7 days</p>
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NDC 49035-345-03
*Compare to the active ingredient in Monistat® 3

M-Zole 3

Combination Pack

Vaginal antifungal

Miconazole nitrate vaginal suppositories, USP 200 mg and Miconazole nitrate vaginal cream, USP 2%

- ✓ Cures most vaginal yeast infections
- ✓ Relieves associated external itching and irritation

3 miconazole nitrate vaginal suppositories, USP 200 mg with 1 reusable applicator plus 1 tube of miconazole nitrate vaginal cream, USP 2%

Net wt. 0.32 oz (9g)

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

Distributed by: (Specific to customer's labeling guide.
Most state either: manufacturer, packer, or distributor)

Product of Spain
Product of Italy



MICONAZOLE 3 COMBINATION PACK

miconazole nitrate kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49035-345
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49035-345-03	1 in 1 PACKAGE, COMBINATION; Type 0: Not a Combination Product	05/01/2020	

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	05/01/2020	

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)	
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	05/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA074926	05/01/2020	

