

MICONAZOLE 3 COMBINATION PACK- miconazole nitrate
Cardinal Health (Leader) 37205

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 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. 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 room temperature 15°-30°C (59°-86°F). Avoid heat (over 30°C - 86°F)

Inactive ingredients

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

Questions?

1-800-432-8534 between 9 am and 4 pm EST, Monday-Friday.

Principal Display Panel

NDC 37205-583-03

LEADER®

3 DAY TREATMENT

Disposable Applicators

VAGINAL SUPPOSITORIES plus CREAM for EXTERNAL RELIEF

Compare to

Monistat® 3

active ingredient*

Miconazole 3

Combination Pack

Miconazole Nitrate Vaginal Suppositories, USP 200 mg and

Miconazole Nitrate External Vulvar Cream, 2%

VAGINAL ANTIFUNGAL

Cures most vaginal yeast infections

Relieves associated external itching and irritation

3 Miconazole Nitrate Vaginal suppositories, USP 200 mg plus

1 tube of Miconazole Nitrate External Vulvar Cream - NET WT 0.32 oz (9 g)

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Miconazole 3

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

73100913G1 VC101980 Made in USA

All Leader® Brand products are 100% satisfaction guaranteed
or return to place of purchase for a full refund.

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DUBLIN, OHIO 43017
CIN 2868495
www.myleader.com
1-800-200-6313



0 6295 10785 2

Questions? 1-800-432-8534 between 9 am and 4 pm EST, Monday-Friday.

• external cream: benzoyl peroxide, mineral oil, polyoxyethylene glycol, purified water
• suppository: hydroxyethylcellulose, polyethylene glycol, purified water
• inactive ingredients

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• do not purchase if carton is open
• store at room temperature 15°-30°C (59°-86°F). Avoid heat (over 30°C - 86°F).

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• adults and children 12 years of age and over:
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• directions

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.
If pregnant or breastfeeding, ask a health professional before use.

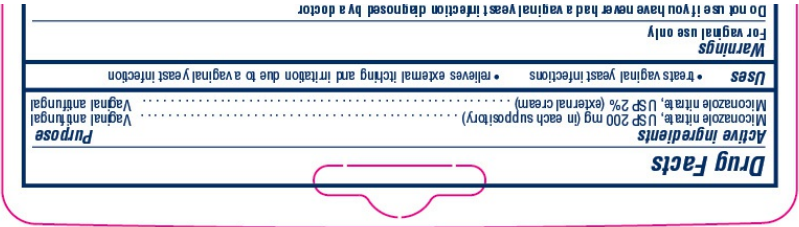
Stop use and ask a doctor if:
• symptoms do not get better in 3 days
• symptoms last more than 7 days
• symptoms of vaginal pain, fever, chills, nausea, vomiting, or foul-smelling vaginal discharge

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

Ask a doctor or pharmacist before use if you are taking the prescription blood thinning medicine warfarin, because bleeding or bruising may occur.

• been exposed to the human immunodeficiency virus (HIV) that causes AIDS
• 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.
• lower abdominal, back or shoulder pain, fever, chills, nausea, vomiting, or foul-smelling vaginal discharge. You may have a more serious condition.

Ask a doctor before use if you have:
• vaginal itching and discomfort for the first time



MICONAZOLE 3 COMBINATION PACK

miconazole nitrate kit

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37205-583

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37205-583-03	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
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
MICONAZOLE NITRATE (UNII: VW4H1CYW1K) (MICONAZOLE - UNII: 7NNO0D7S5M)			MICONAZOLE NITRATE
			200 mg

Inactive Ingredients	
Ingredient Name	

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
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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)	
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	12/02/2002	

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ANDA	ANDA074926	12/02/2002	

Labeler - Cardinal Health (Leader) 37205 (097537435)

Revised: 11/2022

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