MICONAZOLE 3 COMBINATION PACK- miconazole nitrate Cardinal Health (Leader) 70000

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 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 foulsmelling 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 after each 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 polyoxylglycerides, pegoxol 7 stearate, purified water

Questions?

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

Principal display panel

COMPARE TO MONISTAT® 3 active ingredient*

Miconazole 3

Combination ack

Miconazole Nitrate Vaginal Suppositories, SP 200 mg

and Miconazole Nitrate Vaginal Cream, USP 2%

Vaginal Antifungal

Cure 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%

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

DISTRIBUTED BY

CARDINAL HEALTH

DUBLIN, OHIO 43017

www.myleader.com

Package label

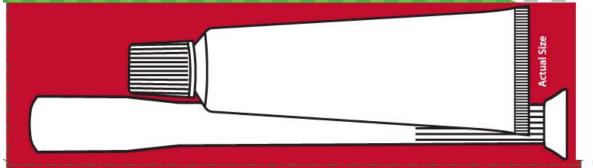


Miconazole 3 **Combination Pack**

3 Vaginal Suppositories with Reusable Applicator Plus External Cream for Itch Relief

COMPARE TO MONISTAT® 3 active ingredient*

100% Money **Back Guarantee**



LEADER

NDC 70000-0025-1

Miconazole 3 Combination Pack

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

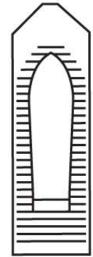
Cures Most Vaginal Yeast Infections Relieves Associated External Itching and Irritation

3 Miconazole Nitrate Vaginal Suppositories, USP 200 mg with 1 Reusable Applicator Plus 1 Tube of Miconazole Nitrate Vaginal Cream, USP 2%

COMPARE TO MONISTAT® 3 active ingredient*

100% Money Back Guarantee

NET WT. 0.32 OZ (9g)



3 Suppositories

Actual Size

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PLD-B654A FC007102 VC710317



Return to place of purchase if not satisfied.



"This product is not affiliated with, manufactured by, or produced by the makers or owners of Monistrate" 3.

Questions? Call 1-877-763-3935 Monday-Friday 9AM-5PM EST

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If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. If swallowed, get medical help or confact a Polson Control C	ндМ гмау.
Stop use and sek a doctor if symptoms do not get better in 3 days symptoms last symptoms last symptoms last	
When using this product me do not lase tampons, douches, spermicides or other vaginal products. Condoms and diaph of not have vaginal infercourse milld increase in vaginal buming, itching or intitation may occur.	and fall to prevent pregnancy or sexually transmitted diseases (STDs).
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Drug Facts	

LEADER Miconazole 3 Cream and Miconazole Nitrate Vaginal Suppositories

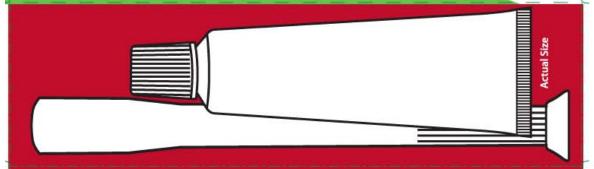
Package label



Miconazole 3 Combination Pack

3 Vaginal Suppositories with Disposable Applicators Plus External Cream for Itch Relief COMPARE TO MONISTAT® 3 active ingredient*

100% Money Back Guarantee



LEADER

NDC 70000-0025-2

Miconazole 3

Combination Pack

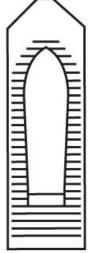
Miconazole Nitrate Vaginal Suppositories, USP 200 mg and Miconazole Nitrate Vaginal Cream, USP 2% Vaginal Antifungal

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% COMPARE TO MONISTAT® 3 active ingredient*

100% Money Back Guarantee

NET WT. 0.32 OZ (9g)



3 Suppositories

Actual Size

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CIN 5520440 REV. 8/20

PLD-B672A FC007132 VC710318

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

suppository: hydrogenated vegetable oll hydroxyanisole, mineral oil, olecyf polyoxylglycerides, pegoxol 7 stearate, punffed water external cream: benzoic acid, butyfated hydroxyanisole, mineral oil, olecyf polyoxylglycerides, pegoxol 7 stearate, punffed water

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LEADER Miconazole 3 Combination Pack

MICONAZOLE 3 COMBINATION PACK

miconazole nitrate kit

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:70000-0025

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000- 0025-1	1 in 1 PACKAGE, COMBINATION; Type 0: Not a Combination Product	07/01/2019	
2	NDC:70000- 0025-2	1 in 1 PACKAGE, COMBINATION; Type 0: Not a Combination Product	07/01/2019	

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	Strengtl

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	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date
ANDA	ANDA074926	07/01/2019	

Part 2 of 2

MICONAZOLE 3

miconazole nitrate cream

Product Information

Route of Administration VAGINAL

Active Ingredient/Active Moiety

ш	7. Carro 11. g. Carro 1. 10. Carro 1.			
	Ingredient Name	Basis of Strength	Strength	
	MICONAZOLE NITRATE (UNII: VW4H1CYW1K) (MICONAZOLE -	MICONAZOLE NITRATE	10 mg	

Inactive Ingredients				
Ingredient Name	Strength			
BENZOIC ACID (UNII: 85KN0B0MIM)				
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)				
MINERAL OIL (UNII: T5L8T28FGP)				
APRICOT KERNEL OIL PEG-6 ESTERS (UNII: DRG3KJZ1TJ)				
PEGOXOL 7 STEARATE (UNII: 3EW5AXE5X5)				
WATER (UNII: 059QF0KO0R)				

Pa	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	07/01/2019			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA074926	07/01/2019		

Labeler - Cardinal Health (Leader) 70000 (063997360)

Revised: 11/2022 Cardinal Health (Leader) 70000