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 foulsmelling 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 polyoxylglycerides, 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 or 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 onio Nitrato Vaginal Suppusitories, USP 200 mg & Misonazalo Kitrate Vaginal Cream, USP 25 VAGINAL ANTIFUNGAL 3-DAY TREATMENT Vaginal suppositories with 3 disposable applicators plus external cream for itch relief

COMBINATION PACK

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



I NICONZOLE NITRATE VAGINAL SUPPOSITORIES, USP 200 mg WITH 3 disposable applicators plus 1 tube of Miconazole NITRATE VAGINAL CREAM, USP 7% - NET WT. 0.32 07 (5 o)

3 Suppositories

Actual Size

"This product is not affiliated with, manufactured by, or produced by the makers or owners of Monistate"3. DISTRIBUTED BY: RITE AID, 30 HUNTER LANE, CAMP HILL, PA 17011 www.riteaid.com

PLD-B672A FC007111 VC710319

SATISFACTION GUARANTEE



CINESTIONS? CALL-155-3805 Monday-Friday SAM-SFM EST

suproelicy; hydrogeniska vegdable oli enterus cream: brezeix acid, buylated hydroxyanisoix, mineral oli, decyf polytoylighyontdes, pegnol 7 stearats, purifled water **стине індгедіелі**

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Other information a do not use if suppository wrapper is missing or damaged (each suppository is inclvidually wrapped) m children under 12 years of age; ask a dooter m exponsionhear, isser? 1 suppository into the vegion an beddine for 3 mights in a row. Throw explicitor ways after use.

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exponsionhear, isser? 1 suppository into the vegion and beddine for a might brown the bedding the vegion of the parties Directions m before using this product send the enclosed consumer information itself for complete directions and entire and entire man directions in the send entire many than the enclosed consumer information. if pregnant or breast-bradieg, sals a least's professional before use. Reap out of reach of children: if swellowed, gat needical help or contact a Poison Control Centur (1-600-222-1222) right away. you get a rash or hives, abdominal pain, fever, chills, neusea, vorrifing, or foul-emeting vaginal decharge Stop use and ask a dector if a symptoms do not get better in 3 days a symptoms last more than 7 days m mild incresse in veginal burning, itahing or imitation may occur m do not have vaginal intercourse m do not use ismpone, douches, spemioldes or other vaginal producta. Condoms and deprinagme may be damaged and half to prevent pregnancy or searsity banentified diseases (510s). When using this product Ask a dector or phermecket before use if you are taking the prescription blood thinking medicine wartern, because blooding or bruking may occur. ■ been exposed for the human immunodeficiency virus (MM) that causes ADS weakened immune system. m vaginsi yessi intections often (such as once a month or 5 in 6 months). You could be pregnant or services nuclearlying medical cause for your symptoms, including diabetes or a eved use y is one of your bear and sever in the first sever configuration or several uses and decreased from the manager and the sever configuration or several decreases, was several to the several properties of the several several configuration of the several s Do not use if you have never had a veginal yeast infection diagnosed by a doctor. **гбијше**м** COSCO III proced professe e control procedure procedure and professe control in control procedure and procedure an Mooleoopque rices nij gen 002 92U ,edertin elezanooM Moorezano lameten (A'S 92U ,edertin elezanooM legenátha langali lagenátha langali asodina Active ingredients Drug Facts

RITE AID Vaginal Treatment

MICONAZOLE 3 COMBINATION PACK

miconazole nitrate kit

Product Information

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

Packaging				
# Iter	n Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:	11822- -7	1 in 1 PACKAGE, COMBINATION; Type 0: Not a Combination Product	03/01/2001	

Quant	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

Duad		Infauna	
Prod	luct	Inform	ation

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

- 10 111 g. 0 1110 11 g. 10 111 g. 1			
Ingredient Name	Basis of Strength	Strength	
MICONAZOLE NITRATE (UNII: VW4H1CYW1K) (MICONAZOLE - UNII:7NNO0D7S5M)	MICONAZOLE NITRATE	10 mg in 0.5 g	

Inactive	Ingredients

9		
	Ingredient Name	Strength
RENZOIC ACID (LINII: 85KNOROMIM)		

BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
MINERAL OIL (UNII: T5L8T28FGP)	
APRICOT KERNEL OIL PEG-6 ESTERS (UNII: DRG3KJZ1TJ)	
PEGOXOL 7 STEARATE (UNII: 3EW5AXE5X5)	
WATER (UNII: 059QF0KO0R)	

F	Packaging					
#	tem Code	Package Description	Marketing Start Date	Marketing End Date		
]		9 g in 1 TUBE; Type 0: Not a Combination Product				

Marketing Information				
Marketing Application Number or Monograph Category 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