MICONAZOLE 3 COMBINATION PACK- miconazole nitrate P & L Development, LLC

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 foulsmelling 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. 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?

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

Principal Display Panel

Compare to the active ingredient in Monistat® 3*

miconazole nitrate

Miconazole nitrate vaginal antifungal cream, USP 2%

and Miconazole nitrate vaginal suppositories, USP 200 mg

vaginal antifungal

combination pack

3 day treatment

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

net wt. oz (g) tube

+ 3 suppositories with 3 disposable applicators

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

Distributed by:

PL Developments

200 Hicks Street

Westbury, NY 11590

Package Label





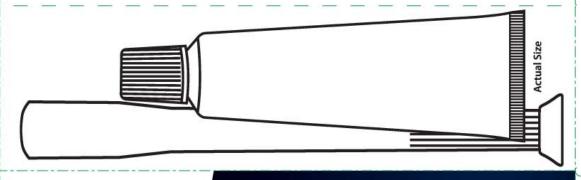
miconazole nitrate

3 day treatment

miconazole nitrate vaginal antifungal cream, USP 2% and miconazole nitrate vaginal suppositories, USP 200 mg

3 day vaginal cream (1 tube) vagi + 3 suppositories with 3 disposable applicators com

vaginal antifungal combination pack





Compare to the active ingredient in Monistat® 3*

NDC 59726-989-03

miconazole nitrate

miconazole nitrate vaginal antifungal cream, USP 2% and miconazole nitrate vaginal suppositories, USP 200 mg

vaginal antifungal combination pack

3 day treatment

- · cures most vaginal yeast infections
- relieves associated external itching and irritation

net wt. 0.32 oz (9 g) tube

+ 3 suppositories with 3 disposable applicators



Distributed by: PL Developments 200 Hicks Street Westbury, NY 11590



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

3 Suppositories

Actual Size

anbbository: hydrogenated vegetable oil зинэрэлбиі өлцэгиі ■ store at 20°-25°C (66°-77°F) [see USP Controlled Room Temperature] excursions permitted to 7°C-30°C (59°-86°F) do not purchase if carton is open do not use if seal over tube opening has been punctured or is not visible Other information • do not use if suppository wrapper is missing or damaged (each suppository is individually wrapped) m children under 12 years of age: ask a doctor m external cream: nee cab to bnucrure sear; Scheesse a small amount of cream onto your flugerith. Holly in lichty, intitisted skin ontaide the vegins. Lee 2 times daily for up to 7 days, ■ suppositories: insert 1 suppository into the vagina at bedtime for 3 nights in a row. Throw applicator away after use. m squitz and children 12 years of age and over: DIRECTIONS Defore using this product read the enclosed consumer information leaflet for complete directions and information Keep out of reach of children. If swallowed, get medical help or contact a Polson Control Center (1-800-222-1222) right away. If pregnant or breast-feeding, ask a health professional before use. ■ you get a rash or hives, abdominal pain, fever, chills, nausea, vomiting, or foul-smelling vaginal discharge Stop use and ask a doctor if usymptoms do not get better in 3 days us symptoms last more than 7 days ■ mild increase in vaginal burning, itching or inflation may occur ■ QO UQC USAG ASBIUSI ILLGECONIZG o not use tampons, douches, spermicides or other vaginal products. Condoms and diaphragms may be damaged and fail to prevent pregnancy or sexually transmitted diseases (S1Ds). When using this product 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 weakened immune system. m vaginal yeast infections often (such as once a month or 3 in 6 months). You could be pregnant or have a senous underlying medical cause for your symptoms, including diabetes or a m jower abdominal, back, or shoulder pain, fever, chills, nausea, vomiting, or foul-smelling vaginal discharge. You may have a more serious condition. ■ vaginal itching and discomfort for the first time Ask a doctor before use if you have Do not use if you have never had a vaginal yeast intection diagnosed by a doctor. For vaginal use only Warnings USBS II treats vaginal yeast infections III relieves external itching and irritation due to a vaginal yeast infection legnutions lenigely Miconazole nitrate, USP 2% (external cream). Vaginal antifungal Miconazole nitrate, USP 200 mg (in each suppository). Purpose Active ingredients Drug Facts

READYINCASE Miconazole Nitrate Combination

MICONAZOLE 3 COMBINATION PACK

miconazole nitrate kit

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:59726-989

Item Code Package Description Marketing Start Date

1 NDC:59726989-03 Package Combination Product

Marketing Start Date

Marketing End Date

06/25/2021

Quantity of Parts Part # Package Quantity Total Product Quantity Part 1 1 TUBE 9 g Part 2 1 BLISTER PACK 3

Part 1 of 2

MICONAZOLE 7

miconazole nitrate cream

Product Information

Item Code (Source) NDC:59726-988

Route of Administration VAGINAL

Active Ingredient/Active Moiety Ingredient Name Basis of Strength MICONAZOLE NITRATE (UNII: VW4H1CYW1K) (MICONAZOLE - UNII:7NNO0D7S5M) MICONAZOLE NITRATE 10 mg in 0.5 g

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)		

Product Characteristics			
Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging				
#	ltem 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	ANDA074164	05/01/2020	

Part 2 of 2

MICONAZOLE 3

miconazole nitrate suppository

Product Information

Item Code (Source) NDC:59726-987

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	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date
ANDA	ANDA074926	06/25/2021	

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date
ANDA	ANDA074926	06/25/2021	

Labeler - P & L Development, LLC (800014821)

Revised: 4/2023 P & L Development, LLC