

MICONAZOLE NITRATE- miconazole nitrate suppository
Rebel Distributors Corp

Miconazole Nitrate, Vaginal Suppositories USP, 100 mg

OTC - ACTIVE INGREDIENT SECTION

Miconazole nitrate 100 mg

OTC - PURPOSE SECTION

Vaginal Antifungal

INDICATIONS & USAGE SECTION

Use

- treats vaginal yeast infections

WARNINGS SECTION

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
- 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 by this product and fail to prevent pregnancy or sexually transmitted diseases (STDs).
- do not have vaginal intercourse

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, abdominal pain, fever, chills, nausea, vomiting, or foul-smelling vaginal discharge
- In case of accidental ingestion, seek professional assistance or contact a poison control center immediately.

OTC - PREGNANCY OR BREAST FEEDING SECTION

If pregnant or breast-feeding, ask a health professional before use

OTC - KEEP OUT OF REACH OF CHILDREN SECTION

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

DOSAGE & ADMINISTRATION SECTION

Directions

- before using this product, read the enclosed brochure for complete instructions
- adults and children 12 years of age and over:
 - insert 1 suppository into the vagina at bedtime for 7 nights in a row
 - wash applicator after each use
- children under 12 years of age: ask a doctor

STORAGE AND HANDLING SECTION

- store at 15°-30°C (59°-86°F). Avoid heat over 30°C (86°F).
- do not use if suppository wrapper is missing or damaged (each suppository is individually wrapped)

INACTIVE INGREDIENT SECTION

hydrogenated vegetable oil base

OTC - QUESTIONS SECTION

QUESTION?

call 1-800-922-1038

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Miconazole Nitrate Vaginal Suppositories USP, 100 mg

NDC 42254-295-07

7 Day Treatment

Miconazole Nitrate Vaginal Suppositories USP, 100 mg

Cures Most Vaginal Yeast Infections

Contains 7 Vaginal Suppositories

Drug Facts

Active ingredient (in each vaginal suppository)

Miconazole nitrate 100 mg	Purpose Vaginal antifungal
--	---

Use

- treats vaginal yeast infections

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

- 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 by this product and fail to prevent pregnancy or sexually transmitted diseases (STDs).
- do not have vaginal intercourse

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, 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 brochure for complete instructions
- adults and children 12 years of age and over:
 - insert 1 suppository into the vagina at bedtime for 7 nights in a row
 - wash applicator after each use
- children under 12 years of age: ask a doctor

Drug Facts (continued)

Other information

- store at 15°-30°C (59°-86°F). Avoid heat over 30°C (86°F).
- do not use if suppository wrapper is missing or damaged (each suppository is individually wrapped)

Inactive ingredienthydrogenated vegetable oil base

Drug Facts (continued)

Questions? call 1-800-922-1038

Manufactured by: G&W Laboratories, Inc.

111 Coolidge Street

South Plainfield, NJ 07080

Visit our website @ www.gwlabs.com

Repackaged by: Rebel Distributors Corp.

3607 Old Conejo Rd.

Thousand Oaks, CA 91320

TAMPER-EVIDENT: For your safety each suppository is individually wrapped. If a suppository is unwrapped or there are signs of tampering, **DO NOT USE.**

Peel	Peel	 <p style="font-size: 12px; margin: 0;">NDC 42254-295-07</p> <h2 style="margin: 0;">Miconazole Nitrate 100mg</h2> <h3 style="margin: 0;">#07 Vaginal Suppositories</h3> <p style="font-size: 10px; margin: 5px 0;">Each vaginal suppository contains: Miconazole Nitrate 100mg Vaginal Antifungal</p> <p style="font-size: 10px; margin: 0;">7 Day Treatment</p> <div style="border: 1px solid black; padding: 2px; width: fit-content; margin: 10px auto;">Product ID: SM029507</div> <p style="font-size: 10px; margin: 0;">Mfr. By: G&W Laboratories, Inc. 111 Coolidge Street South Plainfield, NJ 07080</p>	Peel	Peel
<p>Miconazole Nitrate 100mg Rx# Master #07 Vaginal Suppositories Lot #: 000000 Exp. Date: 00/00/00 NDC 42254-295-07 AWP: \$20.50</p> <p>Miconazole Nitrate 100mg Rx# Master #07 Vaginal Suppositories Lot #: 000000 Exp. Date: 00/00/00 NDC 42254-295-07 AWP: \$20.50</p>		<p>Lot #: 000000 Exp. 00/00/00</p>		<p>Miconazole Nitrate 100mg Rx# Master #07 Vaginal Suppositories Lot #: 000000 Exp. Date: 00/00/00 NDC 42254-295-07 AWP: \$20.50</p> <p>Miconazole Nitrate 100mg Rx# Master #07 Vaginal Suppositories Lot #: 000000 Exp. Date: 00/00/00 NDC 42254-295-07 AWP: \$20.50</p>

Distributed by: Physician Partner, Thousand Oaks, CA 91320 www.physicianpartner.com
Store at controlled room temperature 15°-30°C (59°-86°F) Keep medication out of the reach of children.

MICONAZOLE NITRATE

miconazole nitrate suppository

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42254-295(NDC:0713-0197)
Route of Administration	VAGINAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Miconazole Nitrate (UNII: VW4H1CYW1K) (Miconazole - UNII:7NNO0D7S5M)	Miconazole Nitrate	100 ug

Inactive Ingredients

Ingredient Name	Strength
Hydrogenated Coconut Oil (UNII: JY81OXM1OM)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1	NDC:42254-295-07	7 in 1 BOX		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA074414	04/30/1997		

Labeler - Rebel Distributors Corp (118802834)

Registrant - PSS World Medical, Inc. (101822862)

Establishment

Name	Address	ID/FEI	Business Operations
PSS World Medical, Inc.		791528623	REPACK(42254-295)

Establishment

Name	Address	ID/FEI	Business Operations
STAT RX USA LLC		786036330	REPACK(42254-295)

Establishment

Name	Address	ID/FEI	Business Operations
Dispensing Solutions, Inc.		066070785	RELABEL(42254-295) , REPACK(42254-295)

Establishment

Name	Address	ID/FEI	Business Operations
SCRIPT PAK		964420108	RELABEL(42254-295) , REPACK(42254-295)

Establishment

Name	Address	ID/FEI	Business Operations
Keltman Pharmaceuticals, Inc.		362861077	REPACK(42254-295)

Establishment

Name	Address	ID/FEI	Business Operations
Rebel Distirbutors Corp.		118802834	RELABEL(42254-295) , REPACK(42254-295)