MICONAZOLE 7- miconazole nitrate suppository Strategic Sourcing Services LLC

Miconazole Nitrate Vaginal Suppositories, USP

Drug Facts

Active ingredient (in each vaginal suppository)

Miconazole nitrate, USP 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
- vaginal yeast infections often (such as once a month or 3 in 6 months).
 You may have a more serious condition. You could be pregnant or have a medical condition, such as diabetes or a weakened immune system.
- lower abdominal, back, or shoulder pain, fever, chills, nausea, vomiting, or foulsmelling vaginal discharge
- been exposed to the human immunodeficiency virus (HIV) that causes AIDS

Ask a doctor or pharmacist before use if you are

taking a prescription blood thinning medicine, such as warfarin, because bleeding or bruising may occur

When using this product

- do not use tampons, douches, spermicides or other vaginal products
- do not use condoms or diaphragms. They may be damaged by this product and not prevent pregnancy or sexually transmitted diseases (STDs).
- do not have vaginal intercourse (sex)
- mild increase in vaginal burning, itching or irritation may occur

Stop use and ask a doctor if

- side effects occur.
- symptoms do not get better after 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 (1-800-222-1222) right away.

Directions

- before using this product read the enclosed consumer information leaflet for complete instructions and information
- 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 use.
- children under 12 years: ask a doctor

Other information

- do not purchase if carton is open
- each suppository is individually wrapped. Do not use if wrapper is missing or damaged.
- store at 20°-25°C (68°-77°F) [see USP Controlled Room Temperature] excursions permitted to 15°-30°C (59°-86°F).

Inactive ingredient

hydrogenated vegetable oil

Questions?

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

Principal display panel

COMPARETO MONISTAT® 7 ACTIVE INGREDIENT*

miconazole 7

Vaginal Suppositories

Miconazole Nitrate Vaginal

Suppositories, USP 100 mg

Vaginal antifungal

Cures most vaginal yeast infections

7 VAGINAL SUPPOSITORIES WITH 1 REUSABLE PLASTIC APPLICATOR

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

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Memphis, TN 38141

www.sunmarkbrand.com

Package label

sunmark® 🚄

COMPARE TO MONISTAT® 7
ACTIVE INGREDIENT*

NDC 49348-833-61



miconazole 7

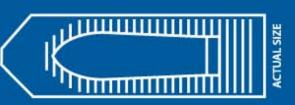
Vaginal Suppositories

7 VAGINAL SUPPOSITORIES WITH 1 REUSABLE PLASTIC APPLICATOR

1 Reusable Plastic Applicator

CTUAL SIZ

7 Suppositories



sunmark® miconazole 7

Vaginal Suppositories

Miconazole Nitrate Vaginal
Suppositories, USP 100 mg
Vaginal antifungal
Cures most vaginal yeast infections

7 VAGINAL SUPPOSITORIES WITH 1 REUSABLE PLASTIC APPLICATOR

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or produced by the makers or owners of Monistat® 7. mild increase in vaginal burning, itching or irritation may occur. "This product is not affiliated with, manufactured by, do not have vaginal intercourse (sex) and not prevent pregnancy or sexually transmitted diseases (STDs). do not use condoms or diaphragms. They may be damaged by this product CINESTIONS? Call 1-877-753-3935 Monday-Friday 9AM-5PM EST ■ do not use tampons, douches, spermicides or other vaginal products When using this product Inactive ingredient hydrogenated vegetable oil blood thinning medicine warfarin, because bleeding or bruising may occur. Temperature] excursions permitted to 15°-30°C (59°-86°F) Ask a doctor or pharmacist before use if you are taking the prescription ■ store at 20°-25°C (68°-77°F) [see USP Controlled Room ■ been exposed to the human immunodeficiency virus (HIV) that causes AIDS or damaged. foul-smelling vaginal discharge each suppository is individually wrapped. Do not use if wrapper is missing lower abdominal, back, or shoulder pain, fever, chills, nausea, vomiting, or ■ do not purchase if carton is open weakened immune system. Other information buedusur or have a medical condition, such as diabetes or a months). You may have a more serious condition. You could be children under 12 years: ask a doctor ■ vaginal yeast infections often (such as once a month or 3 in 6 vagina at bedtime for 7 nights in a row. Wash applicator after use. ■ vaginal itching and discomfort for the first time adults and children 12 years of age and over: insert 1 suppository into the Ask a doctor before use if you have information leaflet for complete instructions and information Directions - before using this product read the enclosed consumer 3 doctor. Do not use if you have never had a vaginal yeast infection diagnosed by Poison Control Center (1-800-222-1222) right away. For vaginal use only Keep out of reach of children. If swallowed, get medical help or contact a Warnings If pregnant or breast-feeding, ask a health professional before use. **USG** Integrated the property of the property nowigud' or toul-smelling vaginal discharge you get a rash or hives, abdominal pain, fever, chills, nausea, lagautitna lanigaV Miconazole nitrate, USP 100 mg.. ■ symptoms last more than 7 days (in each vaginal suppository) ■ symptoms do not get better after 3 days əsodınd Active ingredient Stop use and ask a doctor if side effects occur **Drug Facts** (continued) Drug Facts

SUNMARK Vaginal Suppositories

MICONAZOLE 7

miconazole nitrate suppository

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	Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:49348-833

Route of Administration VAGINAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength

MICONAZOLE NITRATE (UNII: VW4H1CYW1K) (MICONAZOLE - UNII:7NNO0D7S5M) MICONAZOLE NITRATE 100 mg

Inactive Ingredients				
Ingredient Name	Strength			
HYDROGENATED PALM KERNEL OIL (UNII: FM8D1RE2VP)				
PALM KERNEL OIL (UNII: B0S90M0233)				

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49348-833- 61	7 in 1 APPLICATOR; Type 0: Not a Combination Product	12/09/2011	

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
ANDA	ANDA073507	12/09/2011			

Labeler - Strategic Sourcing Services LLC (116956644)

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