

Example Drug Facts Label for Miconazole Nitrate Vaginal Products

There are a number of different miconazole nitrate vaginal products in the marketplace. There are 3- and 7-day treatments, creams and suppositories, and combinations (cream labeled for vaginal and external use, and suppository and external cream). The agency is providing a single example that updates the labeling currently used on various products. This labeling should be used for all products and should be adapted to fit the specific product (i.e., the active ingredient, uses, and directions sections of the labeling).

Drug Facts

[For products containing suppositories only]

Active ingredient (in each vaginal suppository)	Purpose
Miconazole nitrate (___) mg ¹	Vaginal antifungal

[For products containing vaginal cream only]

Active ingredient	Purpose
Miconazole nitrate (___)% ² (___ mg ¹ in each applicator).....	Vaginal antifungal

[For combination products containing suppositories or vaginal cream plus external cream]

Active ingredients	Purpose
Miconazole nitrate (___) mg ¹ in each vaginal suppository [or]	Vaginal antifungal
Miconazole nitrate (___)% ² (___ mg ¹ in each applicator) [and]	Vaginal antifungal
Miconazole nitrate 2% (external cream)	Vaginal antifungal

Use

treats vaginal yeast infections

[For combination products that include external application claims, change “**Use**” to “**Uses**” and add the following:]

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

¹ Insert appropriate number of milligrams

² Insert appropriate number

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 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 foul-smelling 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)
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Stop use and ask a doctor if

- # symptoms do not get better after 3 days
 - # symptoms last more than 7 days
 - # you get a rash, abdominal pain, fever, chills, nausea, vomiting, or foul-smelling vaginal discharge
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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 contact a Poison Control Center right away.

Directions³

before using this product, read the enclosed [insert “brochure“ or “leaflet”] for complete instructions

[If applicable for cream products] # to open tube use cap to puncture seal

adults and children 12 years of age and over:

[Select appropriate directions for single-dosage form or combination products.]

vaginal cream: insert one applicatorful into the vagina at bedtime for [insert "3" or "7" as appropriate] days in a row. [Add, as applicable: (For disposable applicators: "Throw applicator away after use.") (For reusable applicator: "Wash applicator after each use.")]

suppositories: insert one suppository into the vagina at bedtime for [insert “3” or “7” as appropriate] days in a row. Wash applicator after each use.

³ The information for the two age groups may be presented in a table format in accord with 21 CFR 201.66(d)(9) with the first bulleted statement appearing above the top line of the table.

- # **external cream:** 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: ask a doctor
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Other information

- # optional – tamper evident statement(s)
 - # store at 20-25⁰ C (68-77⁰ F). Avoid heat over 30⁰ C (86⁰ F).
 - # optional - see [end or side] panel for lot number and expiration date
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Inactive ingredients [list ingredients in alphabetical order. For combination suppository and external cream products, the inactive ingredients should be listed separately following the headers “vaginal suppositories” and “external cream.” For combination vaginal cream and external cream products, if the inactive ingredients differ, they should be listed separately following the headers “vaginal cream” and “external cream.”]

Questions or comments? call toll free 1-800-XXX-XXXX

NOTE: The **Drug Facts (continued)** title should appear wherever the labeling continues onto another panel of the package.