NEW! NEW! with Cream for Itch Relief

**MONISTAT Combination Pack**

Miconazole Nitrate Vaginal Insert (1200mg) and Miconazole Nitrate Cream (2%)

**Vaginal Antifungal**

Cures most vaginal yeast infections and relieves associated external itching and irritation

**T 1 Soft Gel Vaginal Insert With Applicator**

Net Wt. 0.32 oz. Insert, (9g) Tube

**1 Day Treatment**

If you have any questions or comments, please call 1-877-MONISTAT (1-877-666-4782) or visit our website at www.monistat.com

**Manufactured**

©McNeil-PPC, Inc. 2001

Covered under patent number 5,514,698

Distributed by: Personal Products Company

**Advisory Information**

Miconazole Nitrate Vaginal Insert (1200mg)

1 Soft Gel Vaginal Insert With Applicator

**DIRECTIONS**

1. Insert the vaginal insert:
   - Adults and children 12 years of age and over:
   - If you have never had a vaginal yeast infection diagnosed by a doctor and you get vaginal itching and discomfort for the first time:
   - If you get 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.
   - If you have had a vaginal yeast infection diagnosed by a doctor and you get vaginal itching and discomfort again:
   - If you have already used this product and symptoms do not get better in 3 days

2. Directions:
   - Adults and children 12 years of age and over:
   - Children under 12 years of age: ask a doctor

3. Symptoms do not get better in 3 days:
   - Stop use and ask a doctor if:
   - You get a rash or hives, abdominal pain, fever, chills, nausea, vomiting, or foul-smelling vaginal discharge
   - You have lower abdominal, back or shoulder pain, fever, chills, nausea, vomiting or foul-smelling vaginal discharge. You may have a more serious condition.
   - You have 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.
   - Ask a doctor or pharmacist before use if you are taking the prescription blood thinning medicine warfarin, because bleeding or bruising may occur

4. If pregnant or breast-feeding, ask a doctor before use.

**DRUG FACTS**

**Active ingredients**

Miconazole nitrate 2% (external cream):

- Antifungal

**Purpose**

- Antifungal

**Inactive ingredients**

Gelatin, glycerin, lecithin, mineral oil, titanium dioxide, white petrolatum

**Questions?** If you have any questions or comments, please call 1-877-666-4782

**FDA STANDARD SIZES for Drug Facts**

1 point Helvetica Bold Italic Title
8 point Helvetica Bold Italic Headings
6 point Helvetica Bold Subheads
6 point Helvetica Regular Text
6.5 point Leading
2.5 point hairline
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0.5 point hairline
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Note: All colors for reference only, printer to use pre-approved color drawdowns when printing.

**Fonts:**

- Optima / MathPi / Helv. Condensed

**Family of Companies**

199 Grandview Road
Skillman, NJ 08558-9418
908-874-1666 (Consumer Graphics Dept. Fax)

- This proof indicates approximate color only!
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- This is prepared as a color digital mechanical, no traps have been made.
- All trapping is the responsibility of the engraver and/or separator and/or printer.

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**Consumer**

Graphics Manager: Bridget Motley
Phone: 908.874.2736

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PANTONE® is a registered trademark of Pantone, Inc.
All information contained herein is the CONFIDENTIAL property of Johnson & Johnson and may not be duplicated or released without the expressed written permission of Johnson & Johnson.
Miconazole Nitrate Cream (2%) Relieves External Vulvar Itching & Irritation Due to a Vaginal Yeast Infection

Net Wt. 0.32 oz. (9 grams)

For external vulvar use only. Do not take by mouth or use in eyes. Keep out of reach of children. Before using, read the enclosed leaflet for complete Directions and Warnings.

Directions: To Open:
Use cap to puncture seal. Squeeze a small amount of cream onto your fingertip. Apply to skin outside the vagina (vulva) that itches and is irritated. Use 2 times daily for up to 7 days, as needed.

Tamper Resistant Feature:
The tube opening should be sealed. Do not use if seal has been punctured or embossed design is not visible.

Active Ingredient:
miconazole nitrate 2%.

See end of tube for lot number and expiration date.

Covered under patent Number 5,514,698

Store at 20°C–25°C (68°F–77°F).

Distributed by:
Personal Products Company
Division of McNeil-PPC, Inc., Skillman, NJ 08558
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Substrate:
Consumer

Graphics Manager: Bridgette Motley
Phone: 908.874.2736
Why should I use Monistat® 1 Combination Pack?

A vaginal yeast infection is a common condition caused by an overgrowth of yeast (Candida) that normally live in the vagina’s natural balance. During the growth phase, yeasts become infective and can cause vaginal symptoms such as itching, burning, and discharge. Monistat® 1 Combination Pack may work for you.

What is a vaginal yeast infection?

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How can I prevent repeated vaginal yeast infections?

To lower your chances of getting another vaginal yeast infection:

- To keep the genital area cool and dry. Avoid going to warm, moist areas. The following suggestions may be helpful:
  - Wear cotton underwear and lose-fitting clothing.
  - Change out of damp clothing or wet bedding as soon as possible.
  - If you can reapply when you are not having a menstrual period.
  - Wash your clothes in hot water.
  - Wash your hands before and after handling your undergarments.
  - Avoid the use of tampons.
  - Avoid the use of feminine transvaginal products.
  - Avoid the use of douches or freshen-ers.
  - Avoid the use of vaginal/systemic steroids.
  - Avoid the use of vaginal/systemic antibiotics.
  - Avoid the use of birth control pills.
  - Avoid the use of diaphragms or cervical caps.
  - Avoid the use of intrauterine devices.
  - Avoid the use of antibiotics.
  - Avoid the use of talcum powder.
  - Avoid the use of perfumed products.
  - Avoid the use of deodorants.
  - Avoid the use of soaps.
  - Avoid the use of scented soaps.
  - Avoid the use of cotton.
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How can I get the best results when treating my infection?

- Use the Soft Gel Vaginal Insert at bedtime, even during your menstrual period.
- Use the tube of cream externally only while symptoms are present. If you have symptoms (such as itching and irritation) on the skin inside the vagina itself, apply the cream externally 2 times a day, up to a total of 7 days, as needed.
- Dry the genital area thoroughly after a shower, bath or swim. Change out of a wet bathing suit or damp clothes as soon as possible. A dry area is less likely to lead to the overgrowth of yeast.
- Wear cotton underwear and loose-fitting clothes.
- Wipe from front to back after a bowel movement or after urination.
- Do not use tampons, because they remove some of the drug from the vagina. Use deodorant-free sanitary napkins or pads as needed.
- Do not use spermicides, as they may interfere with Monistat® 1 Combination Pack.
- Do not have vaginal intercourse while using Monistat® 1 Combination Pack.
- Do not scratch the skin outside the vagina. Something can cause more irritation and can spread the infection.

Tell your doctor about any drugs you are taking. Certain drugs such as antibiotics, steroids, and birth control pills, may make it more likely for you to get a vaginal yeast infection. If you are taking any of these drugs do not stop taking them without first talking to a doctor.

If you have any other medical questions or concerns about vaginal yeast infections, call your doctor.

How should I use Monistat® 1 Combination Pack?

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. You may need a different treatment.
- local discomfort, redness, itching, pain, changes in the skin, peeling, oozing, or foul-smelling vaginal discharge. You could have a more serious condition.
- vaginal yeast infections often (such as once a month or more frequent intervals could be a sign of diabetes or a condition that weakens your immune system).
- been exposed to the human immunodeficiency virus (HIV) that causes AIDS.

Ask a doctor or pharmacist before you use:
- any other medicine, even if you feel it is not needed.
- do not use Monistat® 1 Combination Pack:
  - with other medications or products you use on or around the vagina.
  - if you are pregnant or breast-feeding.
  - if you have any other medical questions or concerns about vaginal yeast infections, call your doctor.

What side effects may occur with Monistat® 1 Combination Pack?

The following is not a complete list of possible side effects. Certain side effects may be more likely to occur if you use Monistat® 1 Combination Pack. Call your doctor if you have any of these problems or if you have any other side effects you think may be caused by Monistat® 1 Combination Pack.

- A dry area is less likely to lead to the overgrowth of yeast.
- A mild increase in vaginal burning, itching, or irritation may occur when the Soft Gel Vaginal Insert is inserted. Abdominal cramping has also been reported.

Tell your doctor if you have any of these side effects:
- burning, itching, or irritation or swelling.
- other side effects occur that you think are not listed in this leaflet.

What should I do if I have questions about Monistat® 1 Combination Pack?

If you have any questions about Monistat® 1 Combination Pack or need more information on this product, call our toll-free number. Call between 8:00 AM and 5:00 PM Eastern time, Monday through Friday.

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