### Combos Information

**MONISTAT COMBINATION PACK**

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

- **Uses**: Treats vaginal yeast infections and relieves external itching and irritation due to a vaginal yeast infection.

- **Warnings**: Important warnings include:
  - Do not use if you are pregnant or breastfeeding.
  - Do not use if you have any known allergy to miconazole nitrate.
  - Do not use if you are taking any medicines that thin your blood.
  - Do not use if you have any serious underlying medical conditions.

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

- **Inactive ingredients**: Include:
  - Benzoic acid, cetyl alcohol, isopropyl myristate, polysorbate 60, potassium hydroxide, propylene glycol, purified water, stearyl alcohol.

- **Packaging**: The drug comes in a 0.32 oz (9g) tube plus an applicator.

- **Storage**: Store at room temperature and away from heat and direct light.

### Product Details

- **Net Wt**: 1 OVULE® Insert

### Consumer Information Leaflet

- **Drug Facts**: 1-DAY TREATMENT CURES MOST VAGINAL YEAST INFECTIONS

### Directions for Use

1. Before using this product read the enclosed consumer information leaflet for complete directions and information.

2. Take one vaginal insert the first day of symptoms and one tube of cream with each of the two following days.

3. Use the applicator to insert the vaginal insert into the vagina and apply the cream externally as directed.

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

### Contact Information

Personal Products Company Division of McNeil-PPC, Inc., Skillman, NJ 08558-9418

Phone: 908-874-2992

Graphics Manager: Bryan Petersen

### Font Specifications

- **Fonts**: Arial Black, ITC Zapf Dingbats, Helvetica 53 Extended, Minion Bold, Helvetica Bold, 2.5 point hairline, 2.5 point box hairline, 6 point Helvetica Regular Text, 5 point ITC Zapf Dingbats Bullet, 12 point Helvetica Bold Italic Title, 8 point Helvetica Bold Italic Headings, 10 point Helvetica Bold Italic Title.
Consumer Information Leaflet

VAGINAL ANTHRACNOID
Cures Most Vaginal Yeast Infections
and Relieves Associated External Itching and Irritation

MONISTAT® 1 Combination Pack

Vaginal yeast infections do NOT cause fever, chills, looseness in stools or weight loss, fatigue, unusual vaginal discharge, or a missed period. These may be signs of a sexually transmitted disease (STD) or a total pregnancy. If you have these symptoms, call your doctor right away.

What are other causes of a vaginal discharge?

• It is normal to have a small amount of vaginal discharge at certain times of the month. This normal discharge may be clear or white, and may have a slight fishy smell and does not cause irritation, pain or a foul odor.
• Some medical conditions can weaken the body’s normal ability to fight infection. One of the most common conditions is infection with the human immunodeficiency virus (HIV – the virus that causes AIDS). The HIV virus causes the body to be more likely to get infections, including vaginal yeast infections. That may not occur as easily with proper treatment.
• Other common causes of an abnormal vaginal discharge are: Spermicides may interfere with MONISTAT® 1 Combination Pack.
• Douches and tampons may remove some of the OVULE® Insert and may fail to prevent pregnancy or sexually transmitted diseases (STDs). If you have started treatment and your period occurs, you should complete the full course of treatment.

What causes a vaginal yeast infection?

• Yeast is a common condition caused by an overgrowth of yeast (Candida) that normally lives in the vagina. However, many women have a yeast infection on the skin outside of the vagina (vulva) at the same time that they have a vaginal infection.
• Some women may have a yeast infection on the skin available at the vagina and the vulva at the same time that they have a vaginal infection.
• Yeast infections are more likely to occur if the body’s normal ability to fight infection is weakened. Some medical conditions can weaken the body’s normal ability to fight infection. One of the most common conditions is infection with the human immunodeficiency virus (HIV – the virus that causes AIDS). The HIV virus causes the body to be more likely to get infections, including vaginal yeast infections. That may not occur as easily with proper treatment.
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How can I tell if I have a vaginal yeast infection?

• When you have a vaginal yeast infection, you may have one or more of the following symptoms:
  • vaginal itching
  • vulva itching
  • vaginal discharge that may be thick, white, and lumpy like cottage cheese
  • vaginal soreness, irritation, or burning
  • vaginal yeast infection on the skin outside of the vagina (vulva) at the same time that they have a vaginal infection.

Why should I use MONISTAT® 1 Combination Pack?

MONISTAT® 1 Combination Pack contains a 1-day OVL® Insert that comes most vaginal yeast infections, plus an external cream that can be used for relief of itching and irritation on the outside of the vagina related to a yeast infection. Do not use MONISTAT® 1 Combination Pack during your period, unless you have an STD. See your doctor if you think you have an STD.

What is a vaginal yeast infection?

• A vaginal yeast infection is a common condition caused by an overgrowth of yeast (Candida) that normally lives in the vagina. However, many women have a yeast infection on the skin outside of the vagina (vulva) at the same time that they have a vaginal infection.
• Some women may have a yeast infection on the skin available at the vagina and the vulva at the same time that they have a vaginal infection.
• Yeast infections are more likely to occur if the body’s normal ability to fight infection is weakened. Some medical conditions can weaken the body’s normal ability to fight infection. One of the most common conditions is infection with the human immunodeficiency virus (HIV – the virus that causes AIDS). The HIV virus causes the body to be more likely to get infections, including vaginal yeast infections. That may not occur as easily with proper treatment.
• Other common causes of an abnormal vaginal discharge are: Spermicides may interfere with MONISTAT® 1 Combination Pack.
• Douches and tampons may remove some of the OVULE® Insert and may fail to prevent pregnancy or sexually transmitted diseases (STDs). If you have started treatment and your period occurs, you should complete the full course of treatment.

Who can get a vaginal yeast infection?

• You can get a vaginal yeast infection at any age. It is most common during the childbearing years. Women who are pregnant or diabetic, take antibiotics, birth control pills or steroids, or who have a weakened immune system are more likely to get repeated yeast infections that may not clear up easily with proper treatment.
• Medical conditions can weaken the body’s normal ability to fight infection. One of the most common conditions is infection with the human immunodeficiency virus (HIV – the virus that causes AIDS). The HIV virus causes the body to be more likely to get infections, including vaginal yeast infections. That may not occur as easily with proper treatment. If you may have been exposed to HIV and get repeated vaginal yeast infections, you should see your doctor right away.
• For more information on HIV infection, see the CDC (www.cdc.gov). The CDC has a toll-free information line: 1-800-342-AIDS (English), 1-800-342-HIV (Spanish) or 1-800-232-4636 (TDD). The WHO also has a toll-free information line: 1-800-227-8922.
• Your doctor may call this infection “monilia” or “candidiasis.” Some believe this is a fungus that causes AIDS. The HIV virus causes the body to be more likely to get infections, including vaginal yeast infections. That may not occur as easily with proper treatment.
• Some medical conditions can weaken the body’s normal ability to fight infection. One of the most common conditions is infection with the human immunodeficiency virus (HIV – the virus that causes AIDS). The HIV virus causes the body to be more likely to get infections, including vaginal yeast infections. That may not occur as easily with proper treatment.
• Other common causes of an abnormal vaginal discharge are: Spermicides may interfere with MONISTAT® 1 Combination Pack.
• Douches and tampons may remove some of the OVULE® Insert and may fail to prevent pregnancy or sexually transmitted diseases (STDs). If you have started treatment and your period occurs, you should complete the full course of treatment.

To lower your chances of getting another yeast infection:
• Try to keep the genital area cool and dry. Your skin will naturally be more moist under these conditions. Some people may be more likely to get yeast infections during certain times of the month. This normal discharge may be clear or white, and may have a slight fishy smell and does not cause irritation, pain or a foul odor.
• You may want to see a doctor before taking the drug because someone who is taking it may not be able to get rid of their yeast infection.
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• Try to keep the genital area cool and dry. Your skin will naturally be more moist under these conditions. Some people may be more likely to get yeast infections during certain times of the month.
How can I get the best results when treating my infection?

- Use the OVULE® Insert, even during your menstrual period.
- Use the tube of cream externally only while symptoms are present. If you have symptoms such as itching or irritation on the skin outside the vagina, 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.
- Use clean underwear and lose-fitting clothes.
- Wipe from front to back after a bowel movement or after urination.
- Do not douche, because douching may wash the drug out of the vagina.
- 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. Scratching can cause more irritation and use spread the infection.
- Tell your doctor about any drugs you are now taking. Certain drugs such as antacids, chemotherapy and birth control pills, may affect the way this medicine works. You may need to use different dosages or may need to use this medicine for a different length of time.
- If you have any other medical questions or concerns about vaginal yeast infections, call your doctor.
- What warnings should I know about when using MONISTAT® 1 Combination Pack?

**External Vulvar Cream**

- 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.
  - inner abdominal, back or shoulder pain, fever, chills, nausea, vomiting, or fast-beating vaginal discharge. You could have a more serious condition or an allergic reaction.
- 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.
- vaginal itching and discomfort for the first time. You may need a different treatment.
- vaginal itching and discomfort for the first time. You may need a different treatment.

**OVULE® Insert:

- This product is for adults and children 12 years of age and over. For children under 12 years, ask a doctor.

**Directions for using the Applicator and the OVULE® Insert:

1. Open, grasp and remove container (see picture).

2. Separate the paper backing from blister packet by pushing back the cover from the corner (see picture).

3. Place the OVULE® Insert firmly into the top (wider end) of the applicator so it rests fully.

4. Hold the Applicator containing the OVULE® Insert by the opposite end from where the OVULE® Insert is located.

5. Gently insert the applicator and the OVULE Insert into the vagina as far as it will go comfortably. You can be standing with your feet spread a few inches apart and your knees bent. Or, you can be lying on your back with your knees bent, as shown in the picture.

6. With one hand holding the barrel, use the other hand to push the plunger all the way in to place the OVULE® Insert as far back in the vagina as possible. Then re- move both parts of the applicator from the vagina.

7. Throw away applicator after use. Do not flush in toilet.

You may want to use deodorant-free pads or pantyshields to protect your clothing during the first day you are using MONISTAT® 1 Combination Pack. This will prevent accidental leakage of the cream. If you have symptoms (such as itching and irritation) on the skin outside the vagina, use the External Vulvar Cream twice daily, for up to 7 days as needed.

**How Should I Use MONISTAT® 1 Combination Pack?**

This product is for adults and children 12 years of age and over. For children under 12 years, ask a doctor.

**Directions for using the External Vulvar Cream**

Use the cream twice daily, for up to 7 days as needed.

1. Open the tube by unsealing the cap. The first time the tube is opened, press the sharp point of the cap into the sealed end of the tube. Push the cream firmly until the seal is broken.

2. Squirt a small amount of cream onto your fingertip.

3. Repeat steps 2 – 4, up to two times daily, as needed.

**Stop use and ask your doctor if:**

- symptoms do not get better in 3 days
- symptoms last more than 1 day
- you get a rash or (rarely) allergic reaction, hives, swelling, or use spread the infection.
- tell your doctor about any drugs you are now taking information on what you should do if you have abdominal pain, hives, skin rash, or if you have severe abdominal pain or tenderness.
- What should I do if I have questions about MONISTAT® 1 Combination Pack?

**Other Information:**

- **Tamper-Evident Seal** – do not use if printed sealed pouch or tamper-evident seal shown in the picture is torn, open or incompletely sealed.
- **Active ingredients:** OVULE® Insert: miconazole nitrate, 1200 mg.
- **Inactive ingredients:** external vehicle (Carnauba wax, white petrolatum, dyes, ethyl alcohol, flavor, glycerin, hydroxypropyl methylcellulose, isopropyl myristate, isopropyl palmitate, magnesium stearate, methylcellulose, polyethylene glycol, propylene glycol, purified water, stearyl alcohol.
- **Questions of a medical nature should be taken up with your doctor.
- If you have any other questions or need more information on this product, call our toll-free number 1-877-MONISTAT (1-877-666-4822) during Eastern time, Monday through Friday. A health care specialist will gladly answer your questions. Our toll-free number is 1-877-MONISTAT (1-877-666-4822).
Drug Facts

Active Ingredients:

Miconazole nitrate 1200 mg (in vaginal insert) ...................................................Vaginal antifungal
Miconazole nitrate 2% (external cream) .............................................................Vaginal antifungal

Uses:

For vaginal use only

Do not use on children or a sexual partner unless directed to do so by a doctor.

Directions:

1. Remove from packaging.
2. Remove and discard shield.
3. Hold ointment applicator tube perpendicular to vagina.
4. Insert applicator tube into vagina.
5. Release ointment into vagina.
6. Remove applicator.

For external use only

When using this product:

Do not use on children or a sexual partner unless directed to do so by a doctor.

When using this product:

Do not use on children or a sexual partner unless directed to do so by a doctor.

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

Other Information:

Do not use if shield over tube opening has been punctured or embossed design is not visible
Do not use if seal over tube opening has been tampered with or incomplete

Inactive ingredients:

Burns, diaphragms, or intrauterine devices (IUDs) may be damaged and fail to prevent pregnancy or sexually transmitted diseases (STDs). This treatment does not protect against pregnancy or STDs when used in combination with a sexual partner. Inactive ingredients:

Burns, diaphragms, or intrauterine devices (IUDs) may be damaged and fail to prevent pregnancy or sexually transmitted diseases (STDs). This treatment does not protect against pregnancy or STDs when used in combination with a sexual partner.
Why should I use MONISTAT® 1 Combination Pack with Prefilled Applicator?

- MONISTAT® 1 Combination Pack with Prefilled Applicator contains a 1-dose OVULE® Insert that cures most vaginal yeast infections. It is a very small, insert that is inserted into the vagina and works very fast. It does not require you to use an applicator. The insert can be used in the first few days of your period if you have symptoms.
- MONISTAT® 1 Combination Pack with Prefilled Applicator is 20% smaller than the original MONISTAT® 1 Combination Pack with Prefilled Applicator. The insert is smaller and easier to use, which may make it easier to use even if you have had problems with using an applicator in the past. It does not require you to use an applicator.

What is a vaginal yeast infection?

A vaginal yeast infection is a common condition caused by a fungus called Candida albicans. Women may get a vaginal yeast infection at any age. It is most common during the childbearing years. Women who are pregnant or diabetic, taking antibiotics, birth control pills or steroids, or who have had radiation treatment for breast cancer or other medical conditions such as diabetes or a weakened immune system are more likely to get a vagi

What are other causes of a vaginal discharge?

Other causes of a vaginal discharge are:
- Spermicides may interfere with MONISTAT® 1 Combination Pack with Prefilled Applicator.
- Douches and tampons may remove some of the OVULE® Insert with Prefilled Applicator.
- This drug should fail to prevent pregnancy or sexually transmitted diseases (STDs).
- If you fail to use MONISTAT® 1 Combination Pack with Prefilled Applicator, the insert may remove some of the drug from the vagina.
- Note: Vaginal yeast infections do NOT cause fever, chills, nausea, abdominal pain, or irregular bleeding.
- Itching or a burning sensation in or around the vagina.
- Spermicides may interfere with MONISTAT® 1 Combination Pack with Prefilled Applicator.
- Douches and tampons may remove some of the OVULE® Insert with Prefilled Applicator.
- This drug should fail to prevent pregnancy or sexually transmitted diseases (STDs).
How can I get the best results when treating my infection?

- Do not douche, because douching may wash the drug out of the vagina.
- Wipe from front to back after a bowel movement or after urination.
- Wear cotton underwear and loose-fitting clothes.
- Use the tube of cream externally only while symptoms are present.

How Should I Use MONISTAT® 1 Combination Pack with Prefilled Applicator?

This product is for adults and children 12 years of age and over. For children under 12 years, ask a doctor.

**Directions for using the Applicator containing the OVULE® Insert:**

1. Open pouch and release Prefilled Applicator (see picture). KEEP CONTENTS DRY BEFORE USE.

2. Hold the Applicator containing the OVULE® Insert for the opposite end from where the OVULE® Insert is located.

3. Gently insert the applicator into the vagina as far as it will go comfortably. This can be done while standing, with your knees bent, as shown in the picture.

4. Gently apply the cream up to 2 inches beyond the applicator barrel. Continue to apply the cream even if it may be a little difficult. You may have to bend your knees more for this.

5. Screw the cap back on the tube. Do not flush in toilet.

**Directions for using the External Vulvar Cream**

Use the cream twice daily, for up to 7 days as needed. You may want to use deodorant-free pads or pantyshields with Prefilled Applicator.

- With one hand holding the barrel, use the other hand to push the plunger all the way in to place the OVULE® Insert as far back in the vagina as possible. Then move both parts of the applicator from the vagina.
- You may not flush after use. Do not douche, because douching may wash the drug out of the vagina.

**Side Effects**

- **Common Side Effects:**
  - mild increase in vaginal burning, itching or irritation
  - pain in the lower abdomen, back or shoulder pain
  - fever, chills, nausea, vomiting, or foul-smelling vaginal discharge

- **Less Common Side Effects:**
  - dry area is less likely to lead to the overgrowth of yeast.
  - a dry area is less likely to lead to the overgrowth of yeast.
  - change out of a wet bathing suit or damp clothes as soon as possible.

**How can I keep the cream from leaking out of the tube?**

- Change of a wet bathing suit or damp clothes as soon as possible.
- If you have symptoms (such as itching and irritation) on the skin outside the vagina (vulva) skin, you may want to use deodorant-free pads or pantyshields.

- Stop use and ask your doctor:
  - 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 foul-smelling vaginal discharge.

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

- For vaginal use only.