

MONISTAT 1 COMBINATION PACK TRIPLE ACTION- miconazole nitrate
Insight Pharmaceuticals

Monistat® 1 Combination Pack
Triple Action

Drug Facts

| <i>Active ingredients</i> | <i>Purpose</i> |
|--|-----------------------|
| Miconazole nitrate 1200 mg (in vaginal insert) | Vaginal antifungal |
| Miconazole nitrate 2% (external cream) | Vaginal antifungal |

Uses

- treats vaginal yeast infections
- 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.

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. You may have a more serious condition.**
- 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 and fail to prevent pregnancy or sexually transmitted diseases (STDs).
- do not have vaginal intercourse
- mild increase in vaginal burning, itching or irritation may occur
- if you do not get complete relief ask a doctor before using another product

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 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 right away.

Directions

- before using this product read the enclosed consumer information leaflet for complete directions and information
- adults and children 12 years of age and over:
 - **vaginal insert:** with the applicator, place the vaginal insert into the vagina. Throw applicator away after use.
 - **external cream:** squeeze a small amount of cream onto your fingertip. Apply the cream onto the itchy, irritated skin outside the vagina (vulva). Use 2 times daily for up to 7 days, as needed.
- **children under 12 years of age: ask a doctor**

Other information

- do not use if printed sealed pouch is torn, open or incompletely sealed
- do not use if seal over tube opening has been punctured
- do not purchase if carton is open
- store at 20°-25°C (68°-77°F)
- this is a 1-dose treatment. Most women do not get complete relief of their symptoms in just 1 day. Most women get some improvement in 1 day and complete relief by 7 days.

Inactive ingredients

vaginal insert: gelatin, glycerin, lecithin, mineral oil, titanium dioxide, white petrolatum

external cream: benzoic acid, cetyl alcohol, isopropyl myristate, polysorbate 60, potassium hydroxide, propylene glycol, purified water, stearyl alcohol

Questions?

call toll-free **877-666-4782**

Distributed by: INSIGHT Pharmaceuticals, LLC., Trevose, PA 19053

PRINCIPAL DISPLAY PANEL - Kit Carton

MONISTAT®

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

VAGINAL ANTIFUNGAL | COMBINATION PACK

**CLINICALLY PROVEN
MULTI-SYMPTOM RELIEF**

**#1 DOCTOR
RECOMMENDED BRAND†**

- CURES most vaginal YEAST INFECTIONS
- Relieves associated external itching and irritation

**1
1-DAY**

**MAXIMUM
STRENGTH**

**TREATMENT
OVULE®**

Net Wt. 1 OVULE[®] Insert • 0.32oz (9g) tube

COMPLETE THERAPY™

MAXIMUM STRENGTH Day or Night Ovule

Cures the infection Relieves the symptoms FAST!

LESS MESS Ovules®

Ovule stays in place for anytime use!



1 Less Mess Ovule® insert



Itch relief cream



4 Soothing wipes

MONISTAT®

Miconazole Nitrate Vaginal Insert (1200 mg) and Miconazole Nitrate Cream (2%) VAGINAL ANTIFUNGAL | COMBINATION PACK

1

1-DAY TREATMENT OVULE®

MONISTAT®

Miconazole Nitrate Vaginal Insert (1200 mg) and Miconazole Nitrate Cream (2%) VAGINAL ANTIFUNGAL | COMBINATION PACK

1

1-DAY MAXIMUM STRENGTH TREATMENT OVULE®

Net Wt. 1 OVULE® Insert • 0.32oz (9g) tube



#1 DOCTOR RECOMMENDED BRAND†

- CURES most vaginal YEAST INFECTIONS
- Relieves associated external itching and irritation

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

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May be covered under one or more of the following U.S. Patents: 7,104,968, 7,198,612 Made In Belgium

† Based on a 2012 survey among OB/GYNs and primary care physicians who recommend an over-the-counter brand of vaginal yeast treatments.

TAMPER-EVIDENT UNIT DO NOT USE IF PRINTED SEALED POUCH IS TORN, OPEN OR INCOMPLETELY SEALED



SCAN FOR MORE INFORMATION

FOR INFORMATION VISIT OUR WEBSITE AT WWW.MONISTAT.COM FOR INFORMATION IN SPANISH VISIT WWW.MONISTAT.NET

Other information

- do not use if printed sealed pouch is torn, open or incompletely sealed
- do not use if seal over lid opening has been punctured
- do not purchase if carton is open
- store at 20°-25°C (68°-77°F)
- this is a 1-dose treatment. Most women do not get complete relief of their symptoms in just 1 day. Most women get some improvement in 1 day and complete relief by 7 days.

Inactive ingredients

vaginal insert: gelatin, glycerin, hydroxyethylcellulose, methylcellulose, polyethylene glycol, purified water, potassium hydroxide, propylene glycol, purified water, stearic acid, sodium lauryl sulfate, sodium stearoyl sulfonate, titanium dioxide, white petrolatum

external cream: benzocaine, butylparaben, cetyl alcohol, isopropyl myristate, polyorbital 60, stearic acid, titanium dioxide, white petrolatum, xanthan gum

Questions? call 1-877-666-4782

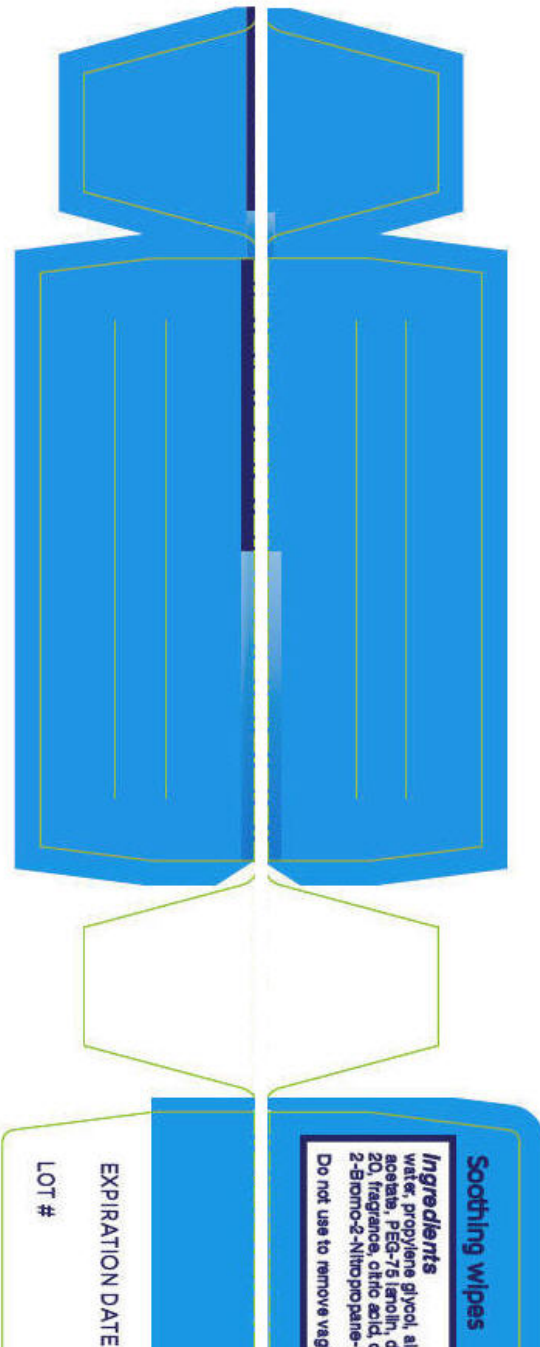
For information, see your doctor or pharmacist. You may have a more serious condition. Vaginal yeast infections often recur as often as once a month or 3 in 6 months. You could be pregnant or have a sex partner with a medical cause for your symptoms. Including diabetes or a weakened immune system. If you have 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 and fail to prevent pregnancy or sexually transmitted diseases (STDs).
- do not have vaginal intercourse.
- do not increase in vaginal burning, itching or irritation may occur.
- if you do not get complete relief, ask a doctor before using another product.
- 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 or hives, abdominal pain, fever, chills, nausea, vomiting, or foul-smelling vaginal discharge.

HOW TO CHOOSE THE RIGHT MONISTAT® FOR YOU

- MONISTAT® is available in 1, 3, or 7 day dosing
- STEP 1: CHOOSE DOSAGE**
- STEP 2: CHOOSE FORM**
- **COMPLETE THERAPY SYSTEM** contains the cure, external itch relief cream and Cool Wipes
 - **CURE & ITCH RELIEF SYSTEM** contains the cure and external itch relief cream
 - **SIMPLE CURE** contains just the cure



Drug Facts

Active ingredients.....
 Monozolo nitrate 1200 mg (in vaginal insert)
 Monozolo nitrate 2% (external cream)
Purpose.....
 Vaginal antifungal
 Vaginal antifungal

Uses
 ■ treats vaginal yeast infections
 ■ relieves external itching and irritation due to a vaginal yeast infection

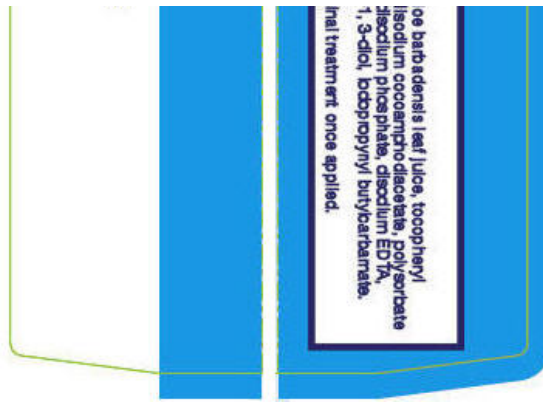
Warnings
 For vaginal use only
 Do not use if you have never had a vaginal yeast infection diagnosed by a doctor.
 Ask a doctor before use if you have
 ■ vaginal itching and discomfort for the first time
 ■ lower abdominal back or discharge pain fever chills nausea vomiting or

Drug Facts (continued)

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 consumer information leaflet for complete directions and information
 ■ adults and children 12 years of age and over:
 ■ vaginal insert: with the applicator, place the vaginal insert into the vagina. Throw applicator away after use.
 ■ external cream: squeeze a small amount of cream onto your fingertip. Apply the cream onto the itchy, irritated skin outside the vagina (vulva).

■ Use 2 times daily for up to 7 days, as needed.
 ■ children under 12 years of age: ask a doctor



MONISTAT 1 COMBINATION PACK TRIPLE ACTION

miconazole nitrate kit

Product Information

| | | | |
|--------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:63736-001 |
|--------------|----------------|--------------------|---------------|

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|-----------------------------|----------------------|--------------------|
| 1 | NDC:63736-001-01 | 1 in 1 PACKAGE, COMBINATION | | |

Quantity of Parts

| Part # | Package Quantity | Total Product Quantity |
|--------|------------------|------------------------|
| Part 1 | 1 POUCH | 1 |
| Part 2 | 1 TUBE | 9 g |

Part 1 of 2

MICONAZOLE NITRATE

miconazole nitrate suppository

Product Information

| | |
|-------------------------|---------|
| Route of Administration | VAGINAL |
|-------------------------|---------|

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--------------------|----------|
| Miconazole Nitrate (UNII: VW4H1CYW1K) (Miconazole - UNII:7NNO0D7S5M) | Miconazole Nitrate | 1200 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|-----------------|----------|
|-----------------|----------|

| | |
|--|--|
| Gelatin (UNII: 2G86QN327L) | |
| Glycerin (UNII: PDC6A3C0OX) | |
| Mineral Oil (UNII: T5L8T28FGP) | |
| Titanium Dioxide (UNII: 15FIX9V2JP) | |
| Petrolatum (UNII: 4T6H12BN9U) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|-----------|---------------------|----------------------|--------------------|
| 1 | | 1 in 1 POUCH | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| NDA | NDA021308 | 06/29/2001 | |

Part 2 of 2

MICONAZOLE NITRATE

miconazole nitrate cream

Product Information

| | |
|--------------------------------|---------|
| Route of Administration | VAGINAL |
|--------------------------------|---------|

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------|--------------|
| Miconazole Nitrate (UNII: VW4H1CYW1K) (Miconazole - UNII:7NNO0D7S5M) | Miconazole Nitrate | 20 mg in 1 g |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| Benzoic Acid (UNII: 8SKN0B0MIM) | |
| Cetyl Alcohol (UNII: 936JST6JCN) | |
| Isopropyl Myristate (UNII: 0RE8K4LNJS) | |
| Polysorbate 60 (UNII: CAL22UVI4M) | |
| Potassium Hydroxide (UNII: WZH3C48M4T) | |
| Propylene Glycol (UNII: 6DC9Q167V3) | |
| Water (UNII: 059QF0KO0R) | |
| Stearyl Alcohol (UNII: 2KR89I4H1Y) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|-----------|---------------------|----------------------|--------------------|
|---|-----------|---------------------|----------------------|--------------------|

| | | | |
|------------------------------|---|-----------------------------|---------------------------|
| 1 | 9 g in 1 TUBE | | |
| Marketing Information | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| NDA | NDA021308 | 06/29/2001 | |
| Marketing Information | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| NDA | NDA021308 | 06/29/2001 | |

Labeler - Insight Pharmaceuticals (176792315)

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------|---------|-----------|------------------------|
| Jubilant | | 246762764 | MANUFACTURE(63736-001) |

Revised: 6/2014

Insight Pharmaceuticals