

**MONISTAT 7 COMBINATION PACK 7-DAY PRE-FILLED APPLICATORS-
miconazole nitrate
Insight Pharmaceuticals LLC**

Monistat 7 Cure Itch Relief - PreFilledApps-Cream

**MONISTAT 7 COMBINATION PACK 7-DAY PRE-FILLED APPLICATORS-
miconazole nitrate
Insight Pharmaceuticals**

MONISTAT® 7 Combination Pack

Drug Facts

Active ingredient

Miconazole nitrate 2%

Miconazole 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 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 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 disease (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:
 - **applicators:** insert 1 applicatorful into the vagina at bedtime for 7 nights in a row. Throw away applicator after use.
 - **external cream:** squeeze a small amount of cream onto your fingertip. 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 of age: ask a doctor

Other information

- do not use if not use if seal over tube opening has been punctured
- do not purchase if carton is open
- store at 20° - 25°C (68° to 77°F)
- Keep this carton for future reference. It contains important information.

Inactive ingredients

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

Questions?

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

PRINCIPAL DISPLAY PANEL - Kit Carton

7- DAY TREATMENT

NEW LOOK!

MONISTAT® 7

Miconazole Nitrate Vaginal Cream (2%) – Vaginal Antifungal
COMBINATION PACK

7- DAY
TREATMENT

CREAM

Cream with 7 Disposable Applicators plus External Cream for Itch Relief

Net Wt. 1.59 oz (45 g) Tube + 0.32 oz (9 g) Tube
+ 7 Disposable Applicators

7-DAY TREATMENT

MONISTAT 7
Miconazole Nitrate Vaginal Cream (2%) – Vaginal Antifungal

COMBINATION PACK

CREAM

TAMPER-EVIDENT UNIT DO NOT USE IF SEAL OVER TUBE HAS BEEN PUNCTURED.

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7-DAY TREATMENT

NEW LOOK!

MONISTAT 7
Miconazole Nitrate Vaginal Cream (2%) – Vaginal Antifungal

COMBINATION PACK

7-DAY TREATMENT

CREAM

Cream with 7 Disposable Applicators + External Cream for Itch Relief

Net Wt. 1.59 oz (45 g) Tube + 0.32 oz (9 g) Tube + 7 Disposable Applicators

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

If you have any questions or comments, please call 1-877-MONISTAT (1-877-666-4782)

7-DAY TREATMENT

MONISTAT 7
Miconazole Nitrate Vaginal Cream (2%) – Vaginal Antifungal

COMBINATION PACK

CREAM

Cream with 7 Disposable Applicators + External Cream for Itch Relief

Drug Facts

| Active ingredient | Purpose |
|--|--------------------|
| Miconazole nitrate 2% | 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 recur as soon as a month or 2 to 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 medication 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 (STD).
- 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

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- adults and children 12 years of age and over:
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 - external cream: squeeze a small amount of cream onto your fingertip. 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 of age: ask a doctor.

Other information

- do not use if seal over tube opening has been punctured
- do not purchase if carbon is visible
- store at 20°-25°C (68°-77°F)
- Keep this carton for future reference. It contains important information.

Inactive ingredients

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

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

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MONISTAT 7 COMBINATION PACK 7-DAY PRE-FILLED APPLICATORS

miconazole nitrate kit

Product Information

| | | | |
|---------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:63736-023 |
|---------------------|----------------|---------------------------|---------------|

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:63736-023-15 | 1 in 1 PACKAGE, COMBINATION; Type 0: Not a Combination Product | 04/26/1993 | |

Quantity of Parts

| Part # | Package Quantity | Total Product Quantity |
|--------|-------------------------|------------------------|
| Part 1 | 7 TUBE, WITH APPLICATOR | 35 g |
| Part 2 | 1 TUBE | 9 g |

Part 1 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 | | 5 g in 1 TUBE, WTH APPLICATOR; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| NDA | NDA017450 | 04/26/1993 | |

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; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| NDA | NDA017450 | 04/26/1993 | |

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| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
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| NDA | NDA017450 | 04/26/1993 | |

Labeler - Insight Pharmaceuticals LLC (055665422)

Revised: 8/2025

Insight Pharmaceuticals LLC