

MONISTAT 3 COMBINATION PACK 3 OVULE INSERTS- miconazole nitrate
Insight Pharmaceuticals LLC

MONISTAT 3 COMBINATION PACK_Ovule inserts-tube_63736-019-03

Drug Facts

Active ingredients

Miconazole nitrate (200 mg in each vaginal insert)

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 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 a disposable applicator, place the insert into the vagina at bedtime for three nights in a row. 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. 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 pouches containing vaginal inserts are 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)
- Keep this carton for future reference. It contains important information.

Inactive ingredients

vaginal insert: gelatin, glycerin, hydrogenated vegetable oil base, titanium dioxide

external cream: 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

MONISTAT® 3 COMBINATION PACK

Miconazole Nitrate Vaginal Inserts (200 mg) and
Miconazole Nitrate Vaginal Cream (2%) – Vaginal Antifungal

3 OVULE® Inserts Net Wt. 2.5 g each
+ 0.32 oz (9 g) Tube

3-DAY TREATMENT

MONISTAT 3
COMBINATION PACK

Miconazole Nitrate Vaginal Inserts (200 mg) and
Miconazole Nitrate Vaginal Cream (2%) – Vaginal Antifungal

OVULE®

3-DAY TREATMENT

NEW LOOK!

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OVULE®

3-DAY TREATMENT

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OVULE®

3 OVULE® Inserts
+
plus External Cream
for Itch Relief

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Drug Facts

Active ingredient
Miconazole nitrate (200 mg in each vaginal insert);
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 recur as often as a month or two if untreated. This could be pregnant or have a serious underlying medical cause for your symptoms, including diabetes, or a weakened immune system. • have exposure 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 (STDs). • do not have vaginal intercourse • mild increases 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

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

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• do not purchase if carton is open • store at 20°-25°C (68°-77°F) • Keep this carton for future reference. It contains important information.

Inactive ingredients
• vaginal insert: glycerin, polyethylene glycol, hydroxyethylcellulose, titanium dioxide
• external cream: benzoic acid, cetyl alcohol, octopargyl myristate, polyethylene glycol, 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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**TAMPER-EVIDENT UNIT
DO NOT USE IF PRINTED
SEALED POUCHES OR
SEAL OVER TUBE ARE
TORN, OPEN, OR
INCOMPLETELY SEALED.**

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

3 OVULE® Inserts Net Wt. 2.5 g each
+ 0.32 oz (9 g) Tube

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

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MONISTAT 3 COMBINATION PACK 3 OVULE INSERTS

miconazole nitrate kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63736-019
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63736-019-03	1 in 1 PACKAGE, COMBINATION; Type 0: Not a Combination Product	04/16/1996	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 KIT	3
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	200 mg

Inactive Ingredients

Ingredient Name	Strength
Gelatin (UNII: 2G86QN327L)	
Glycerin (UNII: PDC6A3C00X)	
Titanium Dioxide (UNII: 15FIX9V2JP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		3 in 1 KIT; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020670	04/16/1996	

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	NDA020670	04/16/1996	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020670	04/16/1996	

Labeler - Insight Pharmaceuticals LLC (055665422)