

MONISTAT TIOCONAZOLE 1- tioconazole ointment
Insight Pharmaceuticals LLC

Monistat Tioconazole Ointment

Drug Facts

Active ingredient (in each applicator)

Tioconazole 300 mg (6.5%)

Purpose

Vaginal antifungal

Uses

- treats vaginal yeast infections

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

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 (1-800-222-1222).

Directions

- before using this product read the enclosed brochure and instructions on foil packet for complete directions and information
- adults and children 12 years of age and over:
 - open the foil packet just before use and remove purple cap
 - insert entire content of applicator into the vagina at bedtime. Throw applicator away after use.
- children under 12 years of age: ask a doctor.

Other information

- this product is a 1-dose treatment. Most women do not get complete relief of their symptoms in just one day. Most women get some improvement in one day and complete relief of symptoms within 7 days.
- if you have questions about vaginal yeast infections, consult your doctor
- store at 20°-25°C (68°-77°F)
- see end flap of carton for lot number and expiration date

Inactive ingredients

butylated hydroxyanisole, magnesium aluminum silicate, white petrolatum

Questions?

1-877-666-4782

PRINCIPAL DISPLAY PANEL

MONISTAT®

Tioconazole Ointment 6.5%

VAGINAL ANTIFUNGAL

Net Wt. 0.16 OZ (4.6 g) PREFILLED APPLICATOR

1-DAY
TREATMENT

Prefilled Ointment



1 Ready-To-Use Prefilled Applicator

**TIOCONAZOLE
OINTMENT 6.5%**

MONISTAT[®]
Tioconazole Ointment 6.5%
VAGINAL ANTIFUNGAL

1

1-DAY
TREATMENT

**TIOCONAZOLE
OINTMENT 6.5%**

MONISTAT[®]
Tioconazole Ointment 6.5%
VAGINAL ANTIFUNGAL

1



• CURES most vaginal YEAST INFECTIONS

1-DAY
TREATMENT
**TIOCONAZOLE
OINTMENT 6.5%**

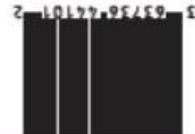
VAGINAL OINTMENT
in 1 Prefilled Applicator

Net Wt. 0.16 oz (4.6g)

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

Dist. by Inlight Pharmaceuticals LLC, Tarrytown, NY 10591
A Prestige Consumer Healthcare Company
Active ingredients: TIOCONAZOLE
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TAMPER-EVIDENT UNIT
DO NOT USE IF SEALED POUCH
PACKET IS TORN, OPEN OR
INCOMPLETELY SEALED



1-DAY
TREATMENT
MONISTAT[®]
Tioconazole Ointment 6.5%
VAGINAL ANTIFUNGAL

Drug Facts (continued)

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away (1-800-422-1222).

Directions
Before using this product, read the enclosed brochure and instructions on printed packet for complete directions and information.
Adults and children 12 years of age and over:
1. Open the printed packet just before use and remove purple cap.
2. Insert the contents of applicator into the vagina at bedtime. Throw applicator away after use.
Children under 12 years of age: ask a doctor.

Other information
This product is a topical treatment. Most women do not experience complete relief of their symptoms in just one day. Most women experience relief within one day and complete relief of symptoms within 7 days.
If you have questions about vaginal yeast infections, consult your doctor.
Store at 20°-25°C (68°-77°F).
See end of carton for lot number and expiration date.

Inactive ingredients
Inactivated myristic acid, magnesium aluminum silicate, white petrolatum.

Questions? 1-877-666-4782

Drug Facts

Active ingredient (in each applicator)
Tioconazole 100 mg (4.5 g)

Use
Use to treat vaginal yeast infections.

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
- bleeding or spotting during your period.
- vaginal yeast infections often last as long as a month or 2 to 3 months. You could be exposed to the human immunodeficiency virus (HIV) that causes AIDS.

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 (STD).
- Do not have vaginal intercourse.
- 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 after 3 days
- symptoms last more than 7 days
- you get a rash or hives, abdominal pain, fever, chills, nausea, vomiting, or
- troubling vaginal discharge.

LOT
EXP

**TIOCONAZOLE
OINTMENT 6.5%**

1

MONISTAT[®]
Tioconazole Ointment 6.5%
VAGINAL ANTIFUNGAL

9357 95029

9357 95029

MONISTAT 11

MONISTAT TIOCONAZOLE 1

tioconazole ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63736-413
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TIOCONAZOLE (UNII: S57Y5X1117) (TIOCONAZOLE - UNII:S57Y5X1117)	TIOCONAZOLE	6.5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
PETROLATUM (UNII: 4T6H12BN9U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63736-413-01	1 in 1 CARTON	11/21/2001	
1		4.6 g in 1 APPLICATOR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA075915	11/21/2001	

Labeler - Insight Pharmaceuticals LLC (055665422)

Revised: 3/2019

Insight Pharmaceuticals LLC