

TIOCONAZOLE 1 DAY- tioconazole ointment
Insight Pharmaceuticals LLC

1-DAY Tioconazole Ointment 6.5%

Drug Facts

Active ingredient (in each applicator)

Tioconazole 300 mg (6.5%)

Purpose

Vaginal antifungal

Use

- 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 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 (STDs).
- do not have vaginal intercourse
- mild increase in vaginal burning, itching or irritation may occur

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 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 brochure and instructions on foil packet for complete

directions and information

- adults and children 12 years and over:
 - open the foil packet just before use and remove purple cap
 - insert entire 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 1-dose treatment, most women do not experience complete relief of their symptoms in just one day. Most women experience some 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 flap of carton for lot number and expiration date

Inactive ingredients

butylated hydroxyanisole, magnesium aluminum silicate, white petrolatum

Questions?

call toll-free **877-666-4782** or **215-273-8755** (collect)

Distributed by: INSIGHT Pharmaceuticals, LLC.
Langhorne, PA 19047-1749

PRINCIPAL DISPLAY PANEL - 4.6g Applicator Carton

1 DAY TREATMENT • PREFILLED APPLICATOR

1-DAY

Tioconazole Ointment 6.5%

VAGINAL ANTIFUNGAL

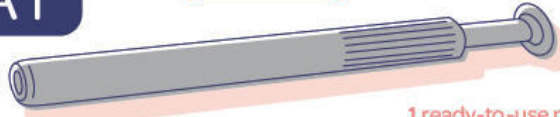
CURES MOST VAGINAL YEAST INFECTIONS

CLINICALLY PROVEN

1 DAY TREATMENT

Net Wt. 4.6g (0.16oz) filled applicator

FROM THE MAKERS OF
MONISTAT®



1 ready-to-use prefilled applicator

1-DAY

Tioconazole Ointment 6.5%
VAGINAL ANTIFUNGAL

CURES MOST VAGINAL YEAST INFECTIONS

1 DAY TREATMENT • PREFILLED APPLICATOR

1-DAY

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CURES MOST VAGINAL YEAST INFECTIONS



1-DAY
Tioconazole Ointment 6.5%
VAGINAL ANTIFUNGAL

Net Wt. 4.6g (0.16oz) filled applicator

EXPIRATION DATE
LOT #
CODE AREA

1 N254 4 JS C3

40-72-1308

distributed by: IN-SIGHT Pharmacy, LLC
Laguna Hills, CA 92653
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TAMPER-EVIDENT UNIT
DO NOT USE IF PRINTED FOIL
PACKET IS TORN, OPEN OR
INCOMPLETELY SEALED

If you have questions or comments,
call 1-877-877-MONISTAT
or 215-273-8755 (collect)
or visit our website at www.monistat.com



SCAN FOR MORE
INFORMATION

VISIT OUR WEBSITE AT WWW.MONISTAT.COM

<p>Drug Facts</p> <p>Active ingredient (in each applicator) Tioconazole 300 mg (6.5%) vaginal antifungal</p> <p>Purpose Treats vaginal yeast infections</p> <p>Use Treats vaginal yeast infections</p> <p>Warnings For vaginal use only</p> <p>Do not use if you have never had a vaginal yeast infection diagnosed by a doctor</p> <p>Ask a doctor before use if you have: vaginal itching and discomfort for the first time vaginal discharge, break or soreness, pain, fever, chills, nausea, vomiting, or foul-smelling 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.</p> <p>When using the product: do not use tampons, douches, spermicides, or other vaginal products, condoms and diaphragms do not have vaginal intercourse stop use and see 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 foul-smelling vaginal discharge</p> <p>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.</p>	<p>Directions Before using the product read the enclosed brochure and instructions on foil packet for complete directions and information.</p> <p>Adults and children 12 years and over: open the foil packet just before use and remove purple cap</p> <p>Insert entire contents of applicator into the vagina at bedtime. Throw applicator away after use.</p> <p>Children under 12 years of age: ask a doctor.</p> <p>Other information This product is a 1-dose treatment. Most women do not experience complete relief of their symptoms in just one day. Most women experience some relief within one day and complete relief of symptoms within 7 days.</p> <p>If you have questions about vaginal yeast infections, consult your doctor.</p> <p>Store at 20° - 25°C (68° - 77°F) Store at 20° - 25°C (68° - 77°F)</p> <p>Inactive ingredients Dulcified hydroxyacetone, magnesium aluminum silicate, white petrolatum</p> <p>See end flap of carton for lot number and expiration date</p> <p>Questions? Call toll-free 877-868-8782 or 215-273-8755 (collect)</p>
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CURES MOST VAGINAL YEAST INFECTIONS

Tioconazole Ointment 6.5%
VAGINAL ANTIFUNGAL

1-DAY

TIOCONAZOLE 1 DAY

tioconazole ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63736-410
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Tioconazole (UNII: S57Y5X1117) (Tioconazole - UNII:S57Y5X1117)	Tioconazole	300 mg in 1 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:63736-410-01	1 in 1 CARTON		
1		1 in 1 POUCH		
1		4.6 g in 1 APPLICATOR		

Marketing Information

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

Labeler - Insight Pharmaceuticals LLC (176792315)

Establishment

Name	Address	ID/FEI	Business Operations
Perrigo		006013346	MANUFACTURE(63736-410)

Revised: 7/2012

Insight Pharmaceuticals LLC