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:
 - o open the foil packet just before use and remove purple cap
 - o 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

Prefilled Ointment

1 Ready-To-Use Prefilled Applicator

TIOCONAZOLE OINTMENT 6.5×

1-DAY

TREATMENT





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VAGINAL ANTIFUNGAL

1-DAY TREATMENT TIOCONAZOLE OINTMENT 6.5%



CURES most vaginal YEAST INFECTIONS

VAGINAL OINTMENT

in 1 Prefilled Applicator

TAMPER-EXPORT UMT DO NOT USE IF SEALED PRINTED PACKET IS TORN, OPEN OR NOOMPLETELY SEALED

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

Dist, by height Pharmaceudicals LLC, Terrytoen, NY 10091 A Prestige Censume Heighton company Active make in billing Moscollates (2015 Toxic direct is owned by height Pharmaceudicals LLC, All rights reserved,



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Drug Facts

VAGINAL ANTIFUNGAL **TATSINOM**

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Drug Facts (continued)

OINTMENT 6.5% LIOCONAZOTE

MONISTAT TIOCONAZOLE 1

tioconazole ointment

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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

mactive ingredients		
Ingredient Name	Strength	
BUTYLATED HYDRO XYANISO LE (UNII: REK4960K2U)		
MAGNESIUM ALUMINUM SILICATE (UNII: 6 M3P6 4 V0 NC)		
PETROLATUM (UNII: 4T6H12BN9U)		

Packaging

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

Marketing Information

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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