TIOCONAZOLE OINTMENT 6.5%- tioconazole ointment
DPT Laboratories, Ltd.

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: 1.Open the foil packet just before use and remove purple cap. 2.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

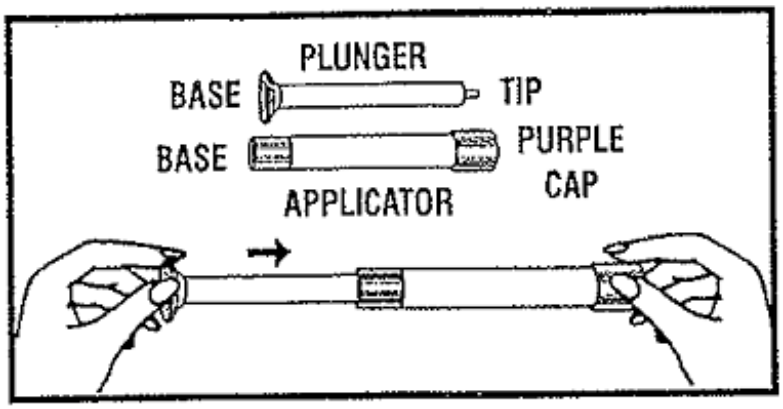
Inactive ingredients
butylated hydroxyanisole, magnesium aluminum silicate, white petrolatum

Do not use if sealed foil packet torn, open, or incompletely sealed.

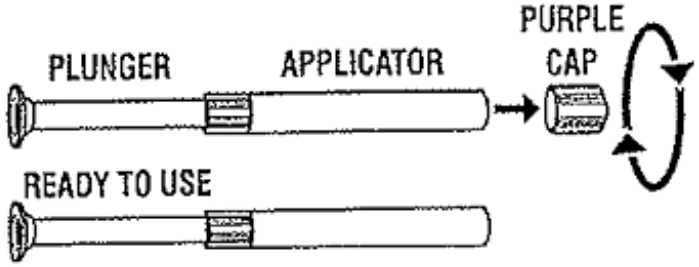
1-DOSE TREATMENT
TIOCONAZOLE OINTMENT 6.5%
VAGINAL ANTIFUNGAL

DIRECTIONS FOR USE

- Tear open foil packet just before using. It is best to use at bedtime.
- Remove applicator and plunger from packet. Applicator is prefilled with vaginal ointment.
- While firmly holding the purple-capped end of the applicator, push the tip of the plunger into the base of applicator.

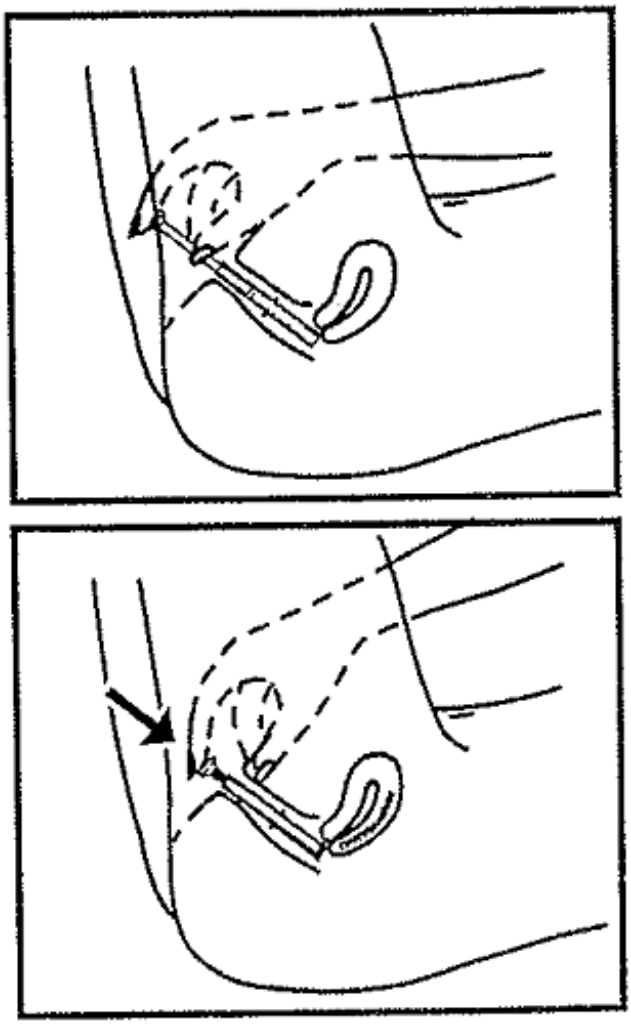


REMOVE PURPLE CAP from top of applicator with a pull-twist action.



Insert the applicator

- Lie on your back with your knees bent. Gently insert applicator into the vagina as far as it will go comfortably.
- Push the plunger into the applicator until it will go no farther. Withdraw the applicator and plunger and dispose of it in the wastebasket. Do not flush.
- DO NOT USE TAMPONS while using this medicine. Use sanitary napkins instead.



PLEASE READ EDUCATIONAL BROCHURE FOR ADDITIONAL INFORMATION.

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DISTRIBUTED BY
PERRIGO
ALLEGAN, MI 48010 U.S.A.

TIOCONAZOLE OINTMENT 6.5%
tioconazole ointment

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63094-0426
Route of Administration	VAGINAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
TIOCONAZOLE (UNII: S57Y5X1117) (TIOCONAZOLE - UNII:S57Y5X1117)	TIOCONAZOLE	65 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:63094-0426-1	5 g in 1 APPLICATOR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA075915	08/22/2007	

Labeler - DPT Laboratories, Ltd. (621782218)

Registrant - DPT Laboratories, Ltd. (621782218)

Establishment

Name	Address	ID/FEI	Business Operations
DPT Laboratories, Ltd.		621782218	manufacture

Revised: 8/2009 DPT Laboratories, Ltd.