Following intravaginal administration of terconazole in humans, absorption ranged from 5 to 8% in three CLINICAL PHARMACOLOGY Terconazole, a triazole derivative, is a white to almost white powder with a molecular weight of 532.47. It is DESCRIPTION Rx only cis containing 80 mg of the antifungal agent terconazole, therefore concurrent use is not recommended. The structural formula of terconazole is as follows: The exact pharmacologic mode of action of terconazole is uncertain; however, it may exert its antifungal Microbiology: Terconazole exhibits fungicidal activity in vitro against Candida albicans; antifungal activity has been demonstrated against other fungi. The MIC values of terconazole against most yeast infections are caused by an overgrowth of yeast organisms that thrive in the vagina. Sometimes the natural balance of beneficial bacteria is upset and an abnormal discharge and/or symptoms develop during successive passages of the yeast. Overgrowth of yeast organisms can occur when the normal balance of beneficial bacteria is upset. Factors that can upset the balance of yeast organisms include heat, tight clothing, antibiotics, and pregnancy. Controlling these factors can help prevent yeast infections. Some of the symptoms that may occur in yeast infections are: Why do yeast infections occur? Yeast infections may also occur if you have: In addition to heat and antibiotics, some of the factors that can cause yeast infections include tight clothing, diabetes, and pregnancy. Controlling these factors can help prevent yeast infections. How can I prevent yeast infections? The structural formula of terconazole is as follows: Terconazole Vaginal Suppositories 80 mg are indicated for the local treatment of vulvovaginal candidiasis. The terconazole vaginal suppositories are self-lubricating and are directed by your doctor. The terconazole vaginal suppositories are self-lubricating and are directed by your doctor. • Temperature: While they are helpful in curing other infections, antibiotics should not be used to treat yeast infections. Consult your physician. Plainfield, NJ 07080 Dist. by: 8-0552TRO1

5-0072 01EVRoZSBDb250cm9sIEdyb3VwBEplYW4A 02 T+mBdgIxNwQxMDAlATIKUEhBUk1BQ09E 03 RQM3MjcA

How to Use Treat Yeast Infections

[continued]
PATIENT INSTRUCTIONS

HOW TO USE:

1. Washing hands first is recommended before using terconazole vaginal suppositories.

2. Using the applicator:
   - Insert the suppository gently into the vagina only.
   - Push the plunger up toward your chest.
   - Lie on your back with your knees drawn up to your chest.
   - With the flat end of the applicator, press the applicator down to break the suppository into the open end flap of carton or suppository label.
   - Remove the applicator. Pull the plunger out of the barrel.

3. Cleaning the applicator:
   - Three oval suppositories, for use inside the vagina only.
   - Place the flat end of the applicator into the open suppository into the applicator. Put the applicator back together by pushing the plunger down toward your chest.

4. After each use, you should thoroughly dry the genital area thoroughly (away from the vagina) after a bowel movement.

5. Dry the genital area thoroughly after changing diapers, bathing or swimming. Change out of a wet bathing suit or damp exercise clothes.

6. Don't douche unless your doctor advises you to do so. The suppository formulation may damage the vagina. Medication leaks.

7. Wipe from front to rear (away from the vagina) after a bowel movement.

8. Don't douche unless your doctor specifically tells you to do so. Douching may disturb the vaginal balance.

9. Don't scratch or rub your vagina. This may lead to a yeast infection. Sometimes monthly changes in hormone levels may lead to yeast infections. If you believe you are pregnant, tell your doctor.

10. Eat nutritious meals to promote your general health.

11. Use your vaginal suppositories, as prescribed by your doctor.

12. Avoid sexual intercourse, if your doctor advises you to do so. The suppository formulation may damage the diaphragm. Therefore, use of the diaphragm during therapy with the vaginal suppository is not recommended.

13. If your partner has any penis itching, rash, or discomfort, he should consult his physician and mention that you are being treated for a yeast infection.

14. You can use the medication even if you are having your menstrual period. However, you should not use tampons because they may absorb the medication.

15. Menstruation: Sometimes monthly changes in hormone levels may lead to yeast infections.

16. Diabetes: In addition to heat and moisture, yeast thrives on sugar. Because diabetes often have sugar in their urine, their vaginas are rich in this substance. Careful control of diabetes may help prevent yeast infection.

17. Controlling these factors can help eliminate yeast infections and may prevent them from coming back.

ADVERSE REACTIONS

Photosensitivity reactions were observed in some normal volunteers following repeated dermal application concentration.

Photosensitivity reactions have not been observed in U.S. and foreign clinical trials in patients who were treated with terconazole vaginal suppositories.

Microbiology:

Terconazole exhibits fungicidal activity by the disruption of normal fungal cell membrane permeability. No resistance to terconazole has been noted in in vitro tests for induction of microbial point mutations (Ames test), or in vivo tests for induction of chromosomal aberrations.

No resistance to terconazole has developed during successive passages of strains of Candida albicans treated with terconazole vaginal suppositories.

The structural formula of terconazole is as follows:

- terconazole 0.8% in pregnant or non-pregnant patients with vulvovaginal candidiasis were also similar to
- the slow rate of absorption, the lack of accumulation, and the mean peak plasma concentration of
- the blood for the parent terconazole was 6.9 hours (range 4.0 to 11.3). Terconazole is extensively
- derived from coconut and/or palm kernel oil (a base of hydrogenated vegetable oils) and butylated
- hydroxyanisole (BHA) and butylated hydroxytoluene (BHT).

General:

Patients known to be hypersensitive to terconazole or to any of the components of the suppositories.

KOH smear and/or cultures) should be repeated to confirm the diagnosis and rule out other pathogens.

If there is lack of response to terconazole, appropriate microbiologic studies (standard

Antibiotics work by eliminating intestinal organisms. While they are helpful in curing other problems, antibiotics may lead to an

overgrowth of Candida in the vagina.

Prevention: Hormonal changes in the body during pregnancy encourage the growth of yeast. This is a very common

time for an infection to occur. Until the baby is born, standardized completely eliminate yeast infections. If you believe

you are pregnant, tell your doctor.

Nursing Mothers:

It is not known whether this drug is excreted in human milk. Animal studies have shown that rat offspring exposed via the

in utero route to terconazole at recommended intravaginal human dose of the suppository formulation) in rats, or 20 mg/kg/day in rabbits, or subcutaneously

up to 20 mg/kg/day in rats.

To determine whether they respond differently from younger subjects. Other reported clinical experience has not identified

whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the

mother.

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Dosages at or below 10 mg/kg/day produced no embryotoxicity; however, there was a delay in fetal ossification at 10

mg/kg/day. A three-week gestation study in rats also revealed some evidence of effecting fetal ossification at

~1280 and

in vitro

for induction of microbial point mutations (Ames test), or

in vivo

for induction of chromosomal aberrations.

Carcinogenesis:

No impairment of fertility occurred when female rats were administered terconazole orally up to 40 mg/kg/day for a three

week period. Male rats did not show a delay in male fertility up to 20 mg/kg/day. Male rabbits (200 mg/kg/day) did not show a delay in male fertility. These results

suggest that terconazole is not carcinogenic.

Impairment of Fertility:

No impairment of fertility occurred when female rats were administered terconazole orally up to 40 mg/kg/day for a three

week period. Male rats did not show a delay in male fertility up to 20 mg/kg/day. Male rabbits (200 mg/kg/day) did not show a delay in male fertility. These results

suggest that terconazole is not carcinogenic.

Teratogenic Effects:

No impairment of fertility occurred when female rats were administered terconazole orally up to 40 mg/kg/day for a three

week period. Male rats did not show a delay in male fertility up to 20 mg/kg/day. Male rabbits (200 mg/kg/day) did not show a delay in male fertility. These results

suggest that terconazole is not carcinogenic.

In vitro testing for the ability of terconazole to induce the formation of tumours did not reveal any evidence of potential for tumour initiation,

development or progression.

In an in vivo test for the ability of terconazole to induce the formation of tumours, no evidence of potential for tumour initiation, development or progression

was observed.

Antimicrobials may remain in the suppository formulation may damage the vagina.

Antibiotics:

Antibiotics work by eliminating intestinal organisms. While they are helpful in curing other problems, antibiotics may lead to an

overgrowth of Candida in the vagina.

Prevention: Hormonal changes in the body during pregnancy encourage the growth of yeast. This is a very common

time for an infection to occur. Until the baby is born, standardized completely eliminate yeast infections. If you believe

you are pregnant, tell your doctor.

Miconazole: Sometimes monthly changes in hormone levels may lead to yeast infections.

Diabetes: In addition to heat and moisture, yeast thrives on sugar. Because diabetes often have sugar in their urine, their vaginas are rich in this substance. Careful control of diabetes may help prevent yeast infection.

Controlling these factors can help eliminate yeast infections and may prevent them from coming back.

Some other tips:

- 1. For best results, be sure to use the medication as prescribed by your doctor, even if you feel better quickly.
- 2. Avoid sexual intercourse, if your doctor advises you to do so. The suppository formulation may damage the diaphragm. Therefore, use of the diaphragm during therapy with the vaginal suppository is not recommended.
- 3. If your partner has any penis itching, rash, or discomfort, he should consult his physician and mention that you are being treated for a yeast infection.
- 4. You can use the medication even if you are having your menstrual period. However, you should not use tampons because they may absorb the medication.

Instead, use external pads or napkins until your menstrual period is over.

- 5. Dry the genital area thoroughly after changing diapers, bathing or swimming. Change out of a wet bathing suit or damp exercise clothes as soon as possible. A dry environment is less likely to encourage the growth of yeast.
- 6. Wear from head to toe away from the infected area.
- 7. Don't douche unless your doctor specifically tells you to do so. Douching may disturb the vaginal balance.
- 8. Don't scratch if you can help it. Scratching can cause more irritation and spread the infection.
- 9. Discuss with your physician any medication you are already taking. Certain types of medication can make your vagina more susceptible to infection.
- 10. Eat nutritious meals to promote your general health.

Dist. by: Tarou Pharmaceuticals U.S.A., Inc., Hawthorne, NY 10532
Mfd. by: G&W Laboratories, Inc., South Plainfield, NJ 07080

Suppositories 80 mg

Terconazole Vaginal Suppositories 80 mg

PATIENT INSTRUCTIONS

HOW TO USE:

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2. Using the applicator:
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   - Push the plunger up toward your chest.
   - Lie on your back with your knees drawn up to your chest.
   - With the flat end of the applicator, press the applicator down to break the suppository into the open end flap of carton or suppository label.
   - Remove the applicator. Pull the plunger out of the barrel.

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9. Discuss with your physician any medication you are already taking. Certain types of medication can make your vagina more susceptible to infection.

10. Eat nutritious meals to promote your general health.

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