Terconazole Vaginal Cream 0.8%

Patient Instructions

3-Day Therapy

Filling the applicator:
1. Remove the cap from the tube.
2. Use the pointed tip on the top of the cap to puncture the seal on the tube.
3. Screw the applicator onto the tube.
4. Squeeze the tube from the bottom and fill the applicator until the plunger stops.
5. Unscrew the applicator from the tube.

Using the applicator:
1. Lie on your back with your knees drawn up toward your chest.
2. Holding the applicator by the ribbed end, insert the filled applicator into the vagina as far as it will comfortably go.
3. Slowly press the plunger of the applicator to release the cream into the vagina.
4. Remove the applicator from the vagina.
5. Apply one applicatorful each night for as many days as directed by your doctor.

Cleaning the applicator:
After each use, you should thoroughly clean the applicator by following the procedure below:
1. Pull the plunger out of the barrel.
2. Wash the pieces with lukewarm, soapy water, and dry them thoroughly.
3. Put the applicator back together by gently pushing the plunger into the barrel as far as it will go.

NOTE: Store at 20°-25°C (68°-77°F) [see USP Controlled Room Temperature]. See end flap for lot number and expiration date.

A Word About Yeast Infections

Why do yeast infections occur?
Yeast infections are caused by an organism called Candida (KAN di duh). It may be present in small and harmless amounts in the mouth, digestive tract, and vagina. Sometimes the natural balance of the vagina becomes upset. This may lead to rapid growth of Candida, which results in a yeast infection. Symptoms of a yeast infection include itching, burning, redness, and an abnormal discharge.

Your doctor can make the diagnosis of a yeast infection by evaluating your symptoms and looking at a sample of the discharge under the microscope.

How can I prevent yeast infections?
Certain factors may increase your chance of developing a yeast infection. These factors don’t actually cause the problem, but they may create a situation that allows the yeast to grow rapidly.

• Clothing: Tight jeans, nylon underwear, pantyhose, and wet bathing suits can hold in heat and moisture (two conditions in which yeast organisms thrive). Looser pants or skirts, 100% cotton underwear, and briefs, 100% cotton, can help.

• Medications: Certain antibiotics can upset the natural balance of the vagina. If you are on antibiotics and develop a yeast infection, tell your doctor.

• Birth control: Certain birth control pills can upset the natural balance of the vagina. If you are on birth control pills and develop a yeast infection, tell your doctor.

• Diabetes: If you have diabetes, you are more likely to develop a yeast infection. If you have diabetes, keep your blood sugar under control to help prevent a yeast infection.

• Insulin injections: If you are giving yourself insulin injections, you may develop infections of the penile skin, penis, or scrotum. These infections usually do not affect the vagina, but they may create a situation that allows the yeast to grow rapidly.

• Devices: If you are using a new plastic device, such as tampons, the natural balance of the vagina may become upset, which can allow yeast to grow.

• Breastfeeding: Breastfeeding can upset the natural balance of the vagina, making it easier for yeast to grow.

• Pregnancy: If you are pregnant, yeast infections are more common. The increased blood flow to your vagina can make the environment more favorable for yeast growth.

• Irregular menstrual periods: If your menstrual periods are irregular, your body’s natural balance may become upset, allowing yeast to grow.

• Multiple sexual partners: If you have multiple sexual partners, your body’s natural balance may become upset, making it easier for yeast to grow.

• Stress: Stress can make your body’s natural balance more favorable for yeast growth.

• Sexual transmission: Yeast can be transmitted from one person to another during sexual activity. If you have a yeast infection, you might want to discuss this with your sexual partner to see if he or she might be able to take steps to prevent infection.

• Immunocompromised: If you are immunocompromised, yeast infections are more common. If you are immunocompromised, talk with your doctor about the best way to prevent yeast infections.

If you have a yeast infection and you do not feel better within a few days, tell your doctor.

ALTANA

Name: Terconazole 0.8% Vaginal Crm
Item # 12347
Dimensions: 6.00” x 8.00”
SSI-20 Colors: Black
UPC/NDC#: 0168-0347-20
Pharmacode: #34

DRAFT for FDA submission, text from innovator/spell checked
Regulatory edits
R & D/Regulatory edits
Regulatory edit
Text changes
Sales edit
Regulatory edit
Regulatory edit

AA-4/9/03
AA-4/15/03
AA-5/1/03
AA-5/5/03
AA-6/3/03
AA-6/10/03
AA-7/29-03
AA-7/30/03
organisms. While they are helpful in curing other problems, they may lead to yeast infections.

- Pregnancy: Terconazole was not mutagenic when tested in vitro for induction of microbial point mutations (Ames test), or for inducing cellular transformation, or in vivo for chromosome breaks (micronucleus test) or dominant lethal mutations in mouse germ cells.
- Impairment of Fertility: No impairment of fertility occurred when female rats were administered terconazole orally up to 40 mg/kg/day for a three month period.

Pregnancy: Teratogenic Effects: Pregnancy Category C:

There was no evidence of teratogenicity when terconazole was administered orally up to 40 mg/kg/day (50 x the recommended intravaginal human dose of the 0.8% vaginal cream formulation) in rats, or 20 mg/kg/day in rabbits, or subcutaneously up to 20 mg/kg/day in rats. Dosages at or below 10 mg/kg/day produced no embryotoxicity; however there was a delay in fetal ossification at 10 mg/kg/day in rats. There was some evidence of embryotoxicity in rabbits and rats at 20-40 mg/kg. In rats, this was reflected as a decrease in litter size and number of viable young and reduced fetal weight. There was also delay in ossification and an increase incidence of skeletal variants.

The no-effect dose of 10 mg/kg/day resulted in a mean peak plasma level of terconazole in pregnant rats of 0.176 mcg/mL which exceeds by 30 times the mean peak plasma level (0.006 mcg/mL) seen in normal subjects after intravaginal administration of terconazole vaginal cream 0.8%. This safety assessment does not account for possible exposure of the fetus through direct transfer to terconazole from the irritated vagina by diffusion across amniotic membranes. Since terconazole is absorbed from the human vagina, it should not be used in the first trimester of pregnancy unless the physician considers it essential to the welfare of the patient.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Animal studies have shown that terconazole administered orally to rats during the first two to three days of lactation produced increased deaths in the offspring of treated dams. Also, offspring of treated dams showed decreased survival during the first few post-partum days, but overall pup weight and weight gain were comparable to or greater than controls throughout lactation. Because many drugs are excreted in human milk, and because of the potential for adverse reaction in nursing infants from terconazole, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use: Safety and efficacy in children have not been established.

Drug Interactions: The therapeutic effect of this product is not affected by oral contraceptive usage.

Carcinogenesis, Mutagenesis, Impairment of Fertility:

Carcinogenesis: Studies to determine the carcinogenic potential of terconazole have not been performed.

Mutagenicity: Terconazole was not mutagenic when tested in vitro for induction of microbial point mutations (Ames test), or for inducing cellular transformation, or in vivo for chromosome breaks (micronucleus test) or dominant lethal mutations in mouse germ cells.

Drug Interactions: The therapeutic effect of this product is not affected by oral contraceptive usage.

OVERDOSAGE: Overdosage of terconazole in humans has not been reported to date. In the rat, the oral LD50 values were found to be 1741 and 849 mg/kg for the male and female, respectively. The oral LD 50 values for the male and female dog were 1260 and 640 mg/kg, respectively.

DOSAGE AND ADMINISTRATION: One full applicatorful (5 g) of terconazole vaginal cream 0.8% is to be administered intravaginally once daily at bedtime for three consecutive days. Before prescribing another course of therapy, the diagnosis should be reconfirmed by smears and/or cultures and other pathogens commonly associated with vulvovaginitis ruled out. The therapeutic effect of terconazole vaginal cream 0.8% is not affected by menstruation.

HOW SUPPLIED: Terconazole Vaginal Cream 0.8% (NDC 0186-0347-20) is available in 20 gram tubes with a measured dose applicator.

Remove this portion before dispensing