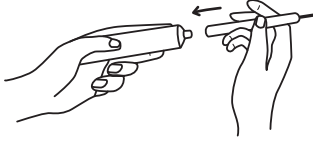


# نشرة للمريضة

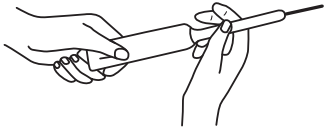
## جينوكونازول كريم مهبلي ٤،٠٠٪ و ٨،٠٠٪ (تيركونازول)

• كيفية إستخدام أداة الإستعمال:  
يوجد مع كل أنبوبة كريم مهبلي أداة إستعمال تستخدم كالتالي:

١- يفتح الغطاء المعدني للأنبوبة بإستخدام ظهر الغطاء البلاستيكي للأنبوبة.



٢- تثبت أداة الإستعمال في الأنبوبة باللف الحلزوني.



٣- يضغط أسفل الأنبوبة حتى تمتلئ الأداة تماماً.

٤- بعد فصل الأنبوبة، تدخل أداة الإستعمال بلطف داخل المهبل قدر الإمكان حسب الرسم الموضح.



٥- يضغط على يد أداة الإستعمال لتفريغ الكريم داخل المهبل ثم اخرجي الأداة.

٦- تغسل الأداة المرفقة بالماء لتستعمل في الجرعات التالية.

# Gynoconazol

## Vaginal Cream & Suppository Terconazole (For vaginal use only)

### COMPOSITION:

**Gynoconazol 0.4% vaginal cream:** contains 0.4% of the antifungal agent terconazole.

**Gynoconazol 0.8% vaginal cream:** contains 0.8% of the antifungal agent terconazole.

**Gynoconazol 80 vaginal suppository:** contains 80 mg of the antifungal agent terconazole.

### CLINICAL PHARMACOLOGY:

- Terconazole exhibits fungicidal activity in vitro against candida albicans. Antifungal activity has also been demonstrated against other fungi.
- Lactobacillus spp., beneficial bacteria found in the human vagina, are not affected by terconazole treatment.
- Terconazole may exert its antifungal activity by the disruption of normal fungal cell membrane permeability.
- No resistance to terconazole has developed during successive passages of candida albicans.

### INDICATIONS:

- Gynoconazol 0.4% vaginal cream is indicated for the local treatment of vulvovaginal candidiasis (moniliasis). Activity also has been demonstrated against other fungi.
- Gynoconazol 0.8% vaginal cream and Gynoconazol 80 vaginal suppository are indicated for the local treatment & prophylaxis of vulvovaginal candidiasis (moniliasis) activity as well as other fungi.

### SIDE EFFECTS:

Side effects are rare & mild in most cases. Most frequently reported were local irritation, pruritus & burning sensation especially at the start of the treatment. Complaints of abdominal pain, fever & skin rash have been reported.

**WARNINGS:** None.

### PRECAUTIONS:

The treatment should be discontinued if local irritation reaction, fever or chills occurred. General hygienic measures should be observed to control sources of infection & re-infection. Appropriate therapy is indicated if the sexual partner is also infected.

### PREGNANCY AND LACTATION:

There are no adequate and controlled studies to date using intravaginal terconazole in women during the first trimester of pregnancy. The drug has been used intravaginally during the second and third trimester of pregnancy without adverse effects on the outcome of pregnancy. However, the drug should be used during pregnancy only when the potential benefits justify the possible risks to the fetus.

### TERATOGENIC EFFECTS:

There was no evidence of teratogenicity when terconazole was administered.

### MUTAGENICITY & CARCINOGENICITY:

There was no evidence of mutagenicity and carcinogenicity.

### NURSING MOTHERS:

It is not known whether this drug is excreted in human milk. 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.

### DOSAGE & ADMINISTRATION:

**Gynoconazol 0.4% Vaginal Cream:**

One full applicator (5 g) should be administered intravaginally once daily at bedtime for seven consecutive days.

**Gynoconazol 0.8% Vaginal Cream:**

- **Treatment:** One full applicator (5 g) should be administered intravaginally once daily at bedtime for three consecutive days.

- **Prophylaxis:** One full applicator (5 g) should be administered intravaginally once weekly at bedtime.

**Gynoconazol 80 Vaginal Suppository:**

One vaginal suppository should be administered intravaginally once daily at bedtime for three consecutive days. The therapeutic effect of these products is not affected by menstruation.

### CONTRAINDICATIONS:

Terconazole vaginal cream and suppositories are contraindicated in individuals who have shown hypersensitivity to terconazole or to any other ingredient of the creams or suppositories.

### PACKAGE AND STORAGE:

**Gynoconazol 0.4%:** 30 g tubes with measured-dose applicator.

**Gynoconazol 0.8%:** 30 g tubes with measured-dose applicator.

**Gynoconazol 80:** 3 vaginal suppositories.

Store at temperature not exceeding 30° C.

Keep All Medicines Out of Reach of Children

Manufactured by: Apex Pharma - S.A.E - Badr City - Egypt.

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