



MICOTER GYNO OVULE

Clotrimazole 500mg

Vaginal Pessary

Read all of this leaflet carefully because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- You must contact a doctor if your symptoms worsen or do not improve in 7 days.
- If you get any side effects after using this product, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Micoter Gyno Ovule is and what it is used for
2. What you need to know before you use Micoter Gyno Ovule
3. How to use Micoter Gyno Ovule
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1. WHAT MICOTER GYNO OVULE IS AND WHAT IT IS USED FOR

This medicinal product contains Clotrimazole, which belongs to a group of medicines called azoles and is an anti-fungal agent which fights the cause of infections such as vaginal thrush.

Micoter Gyno Ovule is a single application for the treatment of vaginal thrush (candidal vaginitis). In the event of associated vulvar involvement, it is recommended to complete vaginal treatment by applying 1% Clotrimazole cream to the lesions. This medicine is only for adults.

You should contact your doctor if your symptoms worsen or do not improve in 7 days.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE MICOTER GYNO OVULE

Do not use Micoter Gyno Ovule:

- If you are allergic to Clotrimazole, azoles or any of the other ingredients of this medicinal product (listed in section 6).
- During your period as it may be less effective.

Warnings and precautions

Talk to your doctor or pharmacist before using Micoter Gyno Ovule:

- If you are unsure whether you have thrush or this is the first time you have had these symptoms
- If you have had more than 2 infections of thrush in the last 6 months
- If you or your partner have ever had a sexually transmitted disease
- If you are aged under 16 or over 60 years of age
- If you have ever had an allergic reaction to Clotrimazole or any other vaginal antifungal products
- If you have any of the following symptoms:
 - o Irregular vaginal bleeding
 - o Abnormal vaginal bleeding or a blood-stained discharge
 - o Ulcers, blisters or sores of the vagina or vulva
 - o Lower abdominal pain
 - o Back or shoulder pain
 - o Pain or difficulty passing urine
 - o Fever or chills
 - o Feeling sick (nausea) or being sick (vomiting)
 - o Diarrhea
 - o A foul-smelling vaginal discharge

This is because Clotrimazole 500mg vaginal pessary may not be the right treatment for you.

Special precautions:

This product may reduce the effectiveness of rubber contraceptives, such as condoms or diaphragms. Consequently, you should use alternative precautions for at least 5 days after using this product.

Do not use tampons, intravaginal douches, spermicides or other vaginal products while using this product.

Avoid vaginal intercourse while you have thrush and during the use of this product because your partner could become infected.

Your doctor may also treat your sexual partner to prevent him from recontaminating you.

Other medicines and MICOTER GYNO OVULE

Clotrimazole may interact with the metabolism of Tacrolimus and Sirolimus. To prevent any risk of overdose with Tacrolimus or Sirolimus, inform your doctor or pharmacist before using MICOTER GYNO OVULE.

Pregnancy and Breast-feeding

MICOTER GYNO OVULE can be used in pregnancy and breastfeeding.

If you are pregnant or think you may be pregnant, ask your doctor or midwife for advice before using this medicinal product.

3. HOW TO USE MICOTER GYNO OVULE

Dosage

Vaginal use, DO NOT SWALLOW.

Treatment consists of one vaginal pessary, which should be inserted into the vagina at night.

Duration of treatment

The symptoms of thrush should disappear within 3 days of treatment.

If symptoms persist beyond 3 days, a second vaginal pessary may be administered.

If no improvement is seen after 7 days, you must tell your doctor.

If you have more than 2 infections within 6 months, you should see your doctor.

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if in doubt.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicinal product can cause side effects, although not everyone gets them.

Seek medical advice immediately if you develop the following symptoms:

Allergic reactions: rash, swelling of the face, throat or tongue, difficulty in swallowing or breathing, weakness, dizziness, fainting, nausea.

After using MICOTER GYNO OVULE, you might experience:

- Vaginal peeling
- Severe itching (pruritus)
- Redness, rashes (erythema)
- At the application site: irritation, swelling or redness, pain
- Discomfort, burning sensation, irritation or vulvovaginal pain
- Vaginal discharge or bleeding
- Stomach pain, nausea

5. HOW TO STORE MICOTER GYNO OVULE

Keep this medicine out of the sight and reach of children.

Store below 30°C in a dry place.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

Each pessary contains:

Clotrimazole 500 mg

Excipient: hard fat 1300mg

This medication comes in the form of a pessary.

Box of 1 pessary.

Marketing Authorization Holder: **Chaoul Pharmaceuticals (CHA-PHA) S.A.L.** – Lebanon

Manufactured by BLISS GVS PHARMA LIMITED - India

For Chaoul Pharmaceuticals (CHA-PHA) S.A.L. – Lebanon (packing)