

## **Package leaflet: Information for the patient**

### **Gynoxin Optima, 200 mg, vaginal capsule, soft**

*Fenticonazole nitrate*

#### **Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 24 hours.

#### **What is in this leaflet**

1. What Gynoxin Optima is and what it is used for
2. What you need to know before you use Gynoxin Optima
3. How to use Gynoxin Optima
4. Possible side effects
5. How to store Gynoxin Optima
6. Contents of the pack and other information

#### **1. What Gynoxin Optima is and what it is used for**

Gynoxin Optima contains fenticonazole as an active substance – imidazole derivative with broad antifungal spectrum.

##### Therapeutic indications

Genital candidiasis called also vulvovaginitis.

Treatment of mixed vaginal infections.

Gynoxin Optima vaginal capsules, soft are intended for vaginal use only.

**Do not take it orally.**

#### **2. What you need to know before you use Gynoxin Optima**

##### **Do not use Gynoxin Optima:**

- if you are allergic to active substance or any of the other ingredients of this medicine (listed in section 6).

##### **Warnings and precautions**

Talk to your doctor or pharmacist if:

- you are pregnant or breastfeeding (see section “Pregnancy, breast-feeding and fertility”).
- you are using a “barrier” method of contraception made of latex. Consequently, you should use alternative precautions while using this product (see section “Other medicines and Gynoxin Optima”).
- You experience any irritation or sensitivity to the product.
- Your symptoms are not reduced within 24 hours or in case of severe or recurrent symptoms.
- Your partner is also affected.
- You had more than two previous infections in the last 6 months.
- You or your partner have ever had a sexually transmitted disease.

- You have ever had hypersensitivity to the active substance or any of the other ingredients of this medicines
- You are aged under 16
- You have any of the following symptoms:
  - Abnormal or irregular vaginal bleeding
  - Blood staining of a vaginal discharge
  - Vulval or vaginal sores, ulcers or blisters
  - Lower abdominal pain or dysuria
  - Adverse effects such as redness, irritation or swelling associated with the treatment.

In case the vaginal capsule is eaten or swallowed, contact a doctor immediately or go to the nearest hospital.

### **Children and adolescents**

Gynoxin Optima is not recommended for children.

### **Other medicines and Gynoxin Optima**

The vaginal capsules contain fat excipients and oils that could damage contraceptives made of latex (condoms, intravaginal rings) (see section “Warnings and precautions”).

### **Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Gynoxin Optima should be used in pregnancy and breastfeeding periods under the supervision of a physician.

### **Driving and using machines**

Gynoxin Optima has no influence on the ability to drive and use machines.

### **Gynoxin Optima contains ethyl parahydroxybenzoate and sodium propyl parahydroxybenzoate**

These substances may cause allergic reactions (possibly delayed).

## **3. How to use Gynoxin Optima**

Always take this medicine exactly as described in this leaflet. Check with your doctor or pharmacist if you are not sure.

Gynoxin Optima vaginal capsules, soft are intended for vaginal use only.

Do not take it orally.

The recommended dose is:

- 1 vaginal capsule, soft, used once daily for 3 days. Insert deeply into vagina at bedtime.

### **If you use more Gynoxin Optima than you should**

There were no cases of overdose.

### **If you forget to use Gynoxin Optima**

Do not take a double dose to make up for a forgotten dose.

### **If you stop using Gynoxin Optima**

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

#### **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

A slight burning sensation may be experienced when the medicine is inserted into the vagina.

When Gynoxin Optima is used as recommended, systemic undesirable reactions are unlikely to occur. Fenticonazole is only poorly absorbed when applied on healthy skin/mucous membrane.

After using this medicine the following adverse reactions can occur:

**Very rare** (<1/10,000)

- vulvovaginal burning sensation
- rash erythematous.

#### **Reporting of side effects**

If you get any side effects, talk to your doctor pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system listed in Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

#### **5. How to store Gynoxin**

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

Do not use this medicine after the expiry date which is stated on the carton and label after EXP. The expiry date refers to the last day of that month.

Do not store above 30°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

#### **6. Contents of the pack and other information**

##### **What Gynoxin contains**

- The active substance is fenticonazole. 1 vaginal capsule, soft contains 200 mg of fenticonazole nitrate.
- The other excipients are: medium-chain triglycerides, precipitated silica, gelatine, glycerine, titanium dioxide, sodium ethyl parahydroxybenzoate, sodium propyl parahydroxybenzoate.

##### **What Gynoxin looks like and contents of the pack**

3 vaginal capsules, soft in PVC/PVDC/Aluminium blister, in carton box.

##### **Marketing Authorisation Holder and Manufacturer**

###### **Marketing Authorisation Holder**

Recordati Industria Chimica e Farmaceutica S.p.A.  
Via Civitali 1  
20148 Milan  
Italy

**Manufacturer**

Catalent Italy S.p.A.  
Via Nettunense km 20, 100  
04011 Aprilia (LT)  
Italy

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Detailed information on this medicine is available on the website of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products

<http://urpl.gov.pl/>