

Package leaflet: Information for the patient

Gynoxin Uno, 600 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 7 days.

What is in this leaflet

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

1. What Gynoxin Uno is and what it is used for

Gynoxin Uno contains fenticonazole as an active substance – imidazole derivative with broad antifungal spectrum, including *Candida*.

Therapeutic indications

Genital candidiasis (thrush) (vulvovaginitis, colpitis, infective discharge).

Treatment of mixed vaginal infections.

Gynoxin Uno is intended for use in adults and adolescents more than 16 years. For treatment in women over 60 years, prior consultation with a physician is required.

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

Do not take it orally.

Only the doctor can make a reliable diagnosis of mycosis and identify the susceptibility of the microorganism to fenticonazole. Refer to information in point 2 of leaflet, when you should talk to the your doctor before start the treatment.

2. What you need to know before you use Gynoxin Uno

Do not use Gynoxin Uno:

- 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 before using Gynoxin Uno if:

- the patient is over 60
- the infection occurred for the first time

- the patient is 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 Uno”).
- you experience any sensitivity to the product.
- symptoms are not reduced within 7 days or if you feel worse
- you had more than 4 previous infections within last year.
- you or your partner have ever had a sexually transmitted disease.
- known hypersensitivity to imidazoles or other vaginal antifungal products
- you have any of the following symptoms:
 - abnormal or irregular vaginal bleeding
 - blood staining of a vaginal discharge
 - vaginal bleeding and (or) pain in shoulders
 - vulval or vaginal sores, ulcers or blisters
 - lower abdominal pain, back pain or dysuria
 - fever ($\geq 38^{\circ}\text{C}$)
 - malodorous discharge
 - nausea
 - adverse effects such as redness, irritation, swelling, erythema, pruritus, rash associated with the treatment.

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

Appropriate therapy is indicated when the partner is also infected.

Children and adolescents

The safety and efficacy of Gynoxin Uno in children under 16 years have not been established. This product is not intended for children and adolescents under 16 years old.

Other medicines and Gynoxin Uno

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

Pregnancy, breast-feeding and fertility

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

Gynoxin Uno is not recommended during pregnancy and breast-feeding, unless otherwise indicated by the physician.

Gynoxin Uno is not recommended in women of childbearing potential not using contraception.

Driving and using machines

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

Gynoxin Uno contains ethyl parahydroxybenzoate and sodium propyl parahydroxybenzoate

These substances may cause allergic reactions (possibly delayed). Should local sensitisation or an allergic reaction occur, the treatment should be discontinued.

3. How to use Gynoxin Uno

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

Gynoxin Uno vaginal capsules, soft are intended for vaginal use only.
Do not take it orally.

The recommended dose is:

Adults and adolescents above 16 years:

For treatment in women over 60 years, prior consultation with a physician is required.

- 1 vaginal capsule, soft, used as a single dose.

Insert deeply into vagina at bedtime. A second administration can be repeated after three days if symptoms persist.

You must talk to a doctor if you do not feel better or if you feel worse after 7 days.

Children and adolescents

Medicinal product Gynoxin Uno is not intended for children and adolescents under 16 years (see “Children and adolescents” in point 2).

If you use more Gynoxin Uno than you should

No cases of overdose have been reported.

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 Uno is used as recommended, active substance is absorbed only slightly and systemic undesirable reactions are unlikely to occur.

After using this medicine the following adverse reactions can occur:

Very rare (<1/10,000)

- vulvovaginal burning sensation
- erythema
- pruritus
- rash

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 Uno

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 Uno contains

- The active substance is fenticonazole. 1 vaginal capsule, soft contains 600 mg of fenticonazole nitrate.
- The other excipients are: liquid paraffin, white vaseline, soy lecithin, gelatine, glycerine, titanium dioxide (E171), ethyl parahydroxybenzoate (E215), sodium propyl parahydroxybenzoate (E217).

What Gynoxin Uno looks like and contents of the pack

1 vaginal capsule, 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

This leaflet was last revised in 03/2020

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/>