

Package leaflet: Information for the patient

Gynoxin, 20 mg/g (2%), vaginal cream

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

1. What Gynoxin is and what it is used for

Gynoxin 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 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 is intended for topical use.

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

Do not use Gynoxin:

- 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 before using Gynoxin 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”).
- 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.

Appropriate therapy is indicated when the partner is also infected.

Children and adolescents

The safety and efficacy of Gynoxin 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

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

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

Driving and using machines

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

Gynoxin contains propylene glycol and hydrogenated lanolin and cetyl alcohol

Propylene glycol may cause skin irritation. Hydrogenated lanolin and cetyl alcohol may cause local skin reaction (e.g. contact dermatitis). Should local sensitisation or an allergic reaction occur, the treatment should be discontinued.

3. How to use Gynoxin

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

Adults and adolescents above 16 years:

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

Insert the applicator's content (approx. 5 g) deeply into vagina. Cream should be applied using the applicator (it is re-usable if washed after use). Apply deeply into vagina once daily at bedtime for 6 days, or twice daily at bedtime and in the morning for 3 consecutive days.

Instruction on administration of the cream

Only clean applicator should be used. Clean the applicator with warm water and soap after each use. In exceptional cases, a physician may advise sterilization of the applicator.

Do not use water at a temperature above 50°C or organic solvents.

Dry the applicator after cleaning and store in attached container.

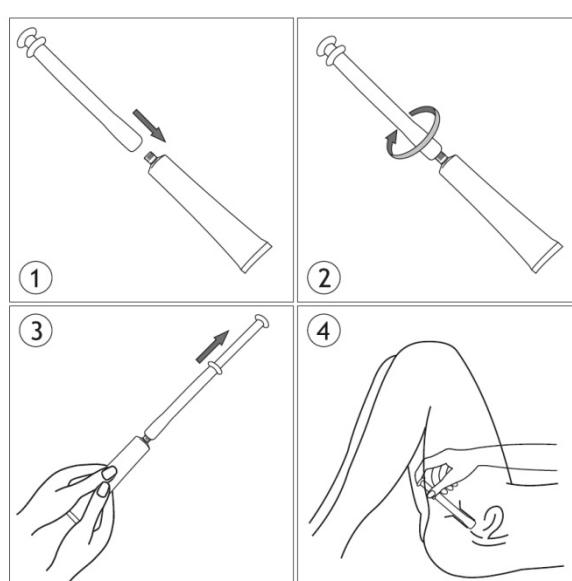
Follow the instructions below (see also the below drawing).

1. After the cap is unscrewed, screw the applicator onto the tube.

2. Squeeze the tube gently at its lower end, so as to fill the applicator. If there is a certain resistance in the piston of the applicator, pull it delicately. Unless otherwise prescribed, the applicator must be fully filled.

3. Remove the applicator from the tube, which then should be closed tightly.

4. Patient should be in a lying down position with knees spread, then the applicator should be inserted deeply into the vagina. Empty the applicator completely by pushing the piston in. Pull the applicator out of the vagina without moving the piston.



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

The sexual partner can also be treated locally with the cream, if necessary (see section "Warnings and precautions" in point 2).

Children and adolescents

Gynoxin is not intended for children and adolescents under 16 years (see section "Children and adolescents" in point 2).

If you use more Gynoxin than you should

There were no cases of overdose.

If you forget to use Gynoxin

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

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 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

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 tube after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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. 100g of vaginal cream contains 2 g of fenticonazole nitrate.
- The other excipients are: fatty acid polyglycol esters, sweet almond oil, propylene glycol, cetyl alcohol, glyceryl monostearate, hydrogenated lanolin, sodium edetate, purified water.

What Gynoxin looks like and contents of the pack

Aluminium tube with interior coated with epoxy-phenolic resin, closed with a plastic cap; in carton box. The package contains the tube with 30 g of cream and applicator (dispenser) which is placed in a plastic, transparent container.

Marketing Authorisation Holder and Manufacturer

Recordati Industria Chimica e Farmaceutica S.p.A.

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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/>