

Package leaflet: Information for the patient

Gynoxin 200 mg vaginal capsules Gynoxin 600 mg vaginal capsules

Fenticonazole nitrate

Read all of this leaflet carefully before you start using this medicine 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.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- 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.

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
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1. What Gynoxin is and what it is used for

Gynoxin contains fenticonazole nitrate. Fenticonazole is an antifungal agent. It slows the growth of some types of fungi and kills some. It is particularly good at killing *Candida albicans*. *Candida* is the organism that causes thrush.

2. What you need to know before you use Gynoxin

Do not use Gynoxin:

- if you are allergic to fenticonazole or any of the other ingredients of this medicine (listed in section 6).
- Gynoxin 600 mg vaginal capsules contains soya lecithin. If you are allergic to peanut or soya, do not use this medicinal product.

Warnings and precautions

Talk to your doctor or pharmacist if:

- You are pregnant or breast-feeding (see section “Pregnancy, breast-feeding and fertility”).
- You are using a “barrier” method of contraception made of latex (see section “Other medicines and Gynoxin”). Consequently, you should use alternative precautions while using this product.
- You are using spermicides, intravaginal douches or other vaginal products (see section “Other medicines and Gynoxin”).
- You experience any irritation or sensitivity to the product.
- Your symptoms are not reduced within one week 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 imidazoles or other vaginal antifungal products.
- You are aged or over 60
- 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, itching or rash associated with the treatment

Children and adolescents

Gynoxin is not recommended for children under 16 years.

Other medicines and Gynoxin

The fatty excipients and oils contained in the vaginal capsules may damage contraceptives made of latex, such as condoms and diaphragms (see “Warnings and precautions” section).

It is not recommended to use spermicides (substance inserted vaginally, that destroys sperm and are used as contraceptive alone or in combination with e.g. diaphragms). Any local vaginal treatment is likely to inactivate a local contraceptive spermicide.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding or think you may be pregnant, ask your doctor for advice before using this medicine. Gynoxin should be used in pregnancy and breast-feeding periods under the supervision of a physician.

Driving and using machines

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

Gynoxin contains:

- ethyl parahydroxybenzoate sodium and sodium propyl parahydroxybenzoate which may cause allergic reactions (possibly delayed).

3. How to use Gynoxin

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is one 200 mg vaginal capsule every day for three days (your symptoms may go away quickly but it is important that you continue using the vaginal capsules for three days) or one 600 mg vaginal capsule for one day. The vaginal capsules should be inserted at bedtime.

- How to insert the vaginal capsule

Lie down, bring your knees up and open your legs. Push the vaginal capsule as deep into the vagina as is comfortable.

Always wash your hands with mild soap and warm water afterwards.

Use in children and adolescents

The dose recommendation for children aged 16 years or above is the same as for adults.

If you use more Gynoxin than you should

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

If you forget to use Gynoxin

Do not use a double dose to make up for a missed dose.

If you stop using Gynoxin

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. This will quickly disappear. When used as recommended, Gynoxin is absorbed only slightly and no side effects involving the entire body (systemic effects) are reported.

The use of medicines for topical use, especially if prolonged, may cause sensitisation (see “Warnings and precautions” section).

The following side effects have been reported with Gynoxin:

Very rare (may affect up to 1 in 10,000 people):

- vulvovaginal burning sensation
- skin erythema, pruritus and rash

Frequency Not Known:

- application site hypersensitivity

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance. Website: hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Gynoxin

Do not store above 30°C. Do not refrigerate or freeze. Store in the original package in order to protect from light.

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

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

Gynoxin 200 mg vaginal capsules

- The active substance is fenticonazole nitrate. 1 vaginal capsule contains 200 mg of fenticonazole nitrate.
- Other ingredients: medium chain triglycerides and colloidal anhydrous silica. The capsule shell contains gelatin, glycerol, titanium dioxide, ethyl parahydroxybenzoate sodium (E215) and sodium propyl parahydroxybenzoate (E217).

Gynoxin 600 mg vaginal capsules

- The active substance is fenticonazole nitrate. 1 vaginal capsule contains 600 mg of fenticonazole nitrate.
- Other ingredients: liquid paraffin, white soft paraffin and soya lethicin. The capsule shell contains gelatin, glycerol, titanium dioxide, ethyl parahydroxybenzoate sodium (E215), sodium propyl parahydroxybenzoate (E217).

What Gynoxin looks like and contents of the pack

Gynoxin vaginal capsules are white opaque soft vaginal capsules packed in a blister pack. Gynoxin vaginal capsules are sold in packs of three.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Recordati Industria Chimica e Farmaceutica SpA, Via M. Civitali, 1-20148 Milano, Italy

Manufacturer:

Catalent Italy S.p.A., via Nettunense Km 20,100, 04011 Aprilia (LT), Italy

This leaflet was last revised in September 2020.