

GYNOXIN 2% VAGINAL CREAM

(fenticonazole nitrate)

Read all of this leaflet carefully before you start using this medicine

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist

In this leaflet:

1. What Gynoxin 2% vaginal cream is and what it is used for
2. Before you use Gynoxin 2% vaginal cream
3. How to use Gynoxin 2% vaginal cream
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1. WHAT GYNOXIN 2% VAGINAL CREAM IS AND WHAT IT IS USED FOR

Gynoxin 2% vaginal cream contains fenticonazole nitrate as the active ingredient, which is an anti-fungal agent.

Gynoxin prevents the growth of certain types of fungi. It is particularly effective against *Candida albicans*, which causes thrush.

2. BEFORE YOU USE GYNOXIN 2% VAGINAL CREAM

You MUST NOT use Gynoxin if you are:

- allergic to fenticonazole nitrate, or other similar medicines known as imidazoles e.g. clotrimazole, or any of the other ingredients (see Section 6, and end of Section 2)

Take special care

- if you are using a barrier method of contraception such as a condom or diaphragm, you should not use Gynoxin.
- when you apply Gynoxin, you may feel a slight burning sensation, but this usually disappears very quickly.
- if you use Gynoxin for prolonged periods of time, you may become allergic to it.

Taking other medicines

Please tell your doctor if you are taking any other medicines, including those obtained without a prescription. Interaction of the cream with other medicines is unlikely.

Pregnancy and breast-feeding

You should tell your doctor if you are pregnant, if you think you are pregnant or if you are breast-feeding. The cream should not be used by pregnant or breast-feeding women unless your doctor advises you.

Driving and using machines

Gynoxin has no effect on your ability to drive or use machines.

Important information about some of the ingredients of Gynoxin

The cream contains the following ingredients:

- **Propylene glycol** (E1520) which may cause skin irritation
- **Lanolin** (wool fat) and **cetyl alcohol** which may cause local skin reactions.

3. HOW TO USE GYNOXIN 2% VAGINAL CREAM

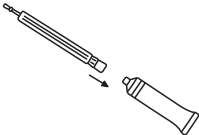
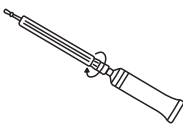
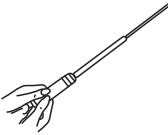

Always use Gynoxin exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The usual dose is one applicator full in the morning and one applicator full in the evening for 3 days. Your symptoms may disappear quickly but it is important that you continue using the cream for 3 days. If there is no improvement, or the condition worsens, consult your doctor.

The use of Gynoxin in children is not recommended.

How to apply Gynoxin

Follow the instructions in the diagrams below:

			
1. Screw the applicator onto the tube in place of the cap.	2. Squeeze the tube gently at its lower end, so as to fill the applicator. If there is a certain resistance in the piston, pull it delicately. Unless otherwise prescribed by the physician, the applicator must be completely filled.	3. Remove the applicator from the tube, which should be closed immediately with the cap.	4. In a lying down position, with knees raised and spread apart, delicately insert the applicator into the vagina as deeply as possible. Push the piston in completely, then pull out the applicator without touching the piston.

Take care to ensure that the applicator is always perfectly clean.

After each use, wash it carefully with warm water and soap. If your doctor advises sterilization of the applicator, for a particular reason, follow his instructions. Do **not** use water which is hotter than 50°C, or solvents. Then dry the applicator and store in its container.

Always wash your hands with mild soap and warm water afterwards. Gynoxin is not greasy, does not soil and can easily be removed with water.

If you use more Gynoxin than you should

If you or someone else has swallowed some Gynoxin by accident, seek medical advice immediately.

If you forget to use Gynoxin

If you forget to apply a dose, do so as soon as you remember and then go on as before. Do not apply a double dose to make up for the forgotten dose.

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

4. POSSIBLE SIDE EFFECTS

Like other medicines, Gynoxin can cause side effects, although not everybody gets them.

You may suffer from mild and transient rash or burning sensations that generally disappear rapidly.

If you use Gynoxin vaginal cream for prolonged periods of time, you may become allergic to it.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

5. HOW TO STORE GYNOXIN 2% VAGINAL CREAM

Keep out of the reach and sight of children.

Do not store above 30°C. Store in the original container. Do not use after the expiry date shown on the outer packaging.

Medicines should not be disposed of via household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Gynoxin 2% vaginal cream contains

The **active** ingredient is fenticonazole nitrate. Each applicator full contains approximately 100mg fenticonazole nitrate.

The **other** ingredients are propylene glycol (E1520), wool fat, almond oil, polyglycolic ester of fatty acids, cetyl alcohol, glyceryl monostearate, disodium edetate and purified water (see end of Section 2: Important information about some of the ingredients of Gynoxin for further information).

What Gynoxin 2% vaginal cream looks like and contents of the pack

Gynoxin is a white cream. It is packaged in an aluminium tube with a plastic cap.

Each tube contains 30g. An applicator is provided; each applicator contains approximately 5g.

Marketing Authorisation Holder and Manufacturer

Recordati Industria Chimica e Farmaceutica SpA
via Matteo Civitali 1-20148 Milan - Italy

This leaflet was last approved in July 2010