

1.3.1 Package Leaflet

PACKAGE LEAFLET: INFORMATION FOR THE USER

Fluomizin 10 mg vaginal tablets Dequalinium chloride

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

1. WHAT FLUOMIZIN IS AND WHAT IT IS USED FOR

Dequalinium chloride, the active ingredient in Fluomizin, belongs to the family of anti-infective and antiseptic drugs. Dequalinium chloride is active against the bacteria which cause bacterial vaginosis.

Fluomizin is used for the treatment of bacterial vaginosis.

It is inserted into the vagina for treatment at the site of infection.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE FLUOMIZIN

Do not use Fluomizin:

- if you are allergic to the active substance dequalinium chloride or any of the other ingredients of this medicine (listed in section 6).
- if you have ulcers on your vagina or cervix.
- if you have not yet had your first period.

Warnings and precautions

Intravaginal use of soaps, spermicides and vaginal douches (vaginal washes) is not recommended during treatment with Fluomizin.

As with all vaginal infections, unprotected sexual intercourse during treatment with Fluomizin is not recommended.

Fluomizin does not reduce the effectiveness of latex condoms.

This product may reduce the effectiveness of non-latex condoms or diaphragms. Consequently, you should use alternative precautions for at least 12 hours following the treatment. Do not use Fluomizin within 12 hours before birth to minimize exposure of the newborn to dequalinium chloride. Please inform your doctor otherwise.

You should stop the treatment during the heavy bleeding period of your menstruation and resume afterwards.

You should talk to your doctor if the symptoms persist at the end of the treatment or in case the symptoms return.

Using other medicines and Fluomizin

Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding

If you are pregnant, think you may be pregnant or plan to have a baby ask your doctor or pharmacist for advice before using Fluomizin.

Tell your doctor or pharmacist if you are breast-feeding or if you plan to breast-feed.

Based on previous experience and since Fluomizin acts locally, no harmful effects on pregnancy and/or the unborn and breast fed infant are expected. Fluomizin should only be used during pregnancy and during breast-feeding if medically needed.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Fluomizin is not likely to affect your ability to drive or operate any machinery. No studies have been performed.

3. HOW TO USE FLUOMIZIN

Always use Fluomizin exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is 1 vaginal tablet daily for 6 days.

Instructions for use

- Use every evening before bed.
- Wash your hands before opening the blister pack.
- Lie down in a reclining position with the legs slightly bent. Insert one vaginal tablet deeply into the vagina.
- You should stop the treatment during the heavy bleeding period of your menstruation and resume afterwards.
- Do not stop treatment early, even if you no longer have any discomfort (e.g. itching, discharge, smell). A treatment of less than 6 days may result in your symptoms returning.
- Fluomizin contains ingredients which do not dissolve completely, and the remains of the tablet are occasionally found in the underwear. This won't affect the effectiveness of the treatment. The tablet will not stain your underwear but for your own comfort you can use a sanitary towel or panty liner.

- If your vagina is dry, the vaginal tablet might not dissolve and be discharged as intact tablet. As consequence, the treatment is not optimal. In this case the vaginal tablet can be moistened with a drop of water before insertion.

If you have the impression that the effect of Fluomizin is too strong or too weak, talk to your doctor or pharmacist.

If you use more Fluomizin than you should

Using a higher daily dose or increasing the recommended duration might increase the risk of vaginal ulcerations.

If you have accidentally used too many vaginal tablets, tell your doctor.

If you forget to use Fluomizin

Do not use a double dose to make up for a forgotten tablet.

If you stop using Fluomizin

A treatment of less than 6 days may result in a relapse. Therefore, do not stop treatment early, even when you have no discomfort (e.g. itching, discharge, smell) anymore.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Fluomizin can cause side effects, although not everybody gets them. Most of the side effects are mild and short lived.

Sometimes the symptoms of vaginal infections (such as itching, burning and discharge) can get worse at the beginning of the treatment, before they start to get better. You should continue with the treatment, but if the complaints persist see your doctor for advice as soon as possible.

Common (may affect up to 1 in 10 people)

- Vaginal discharge; vaginal itching or vaginal burning;
- Vaginal yeast infection (thrush).

Uncommon (may affect up to 1 in 100 people)

- Vaginal bleeding; vaginal pain;
- Inflammation of the vagina (vaginitis),
- Headache;
- Nausea.

Not known (cannot be estimated from the available data)

- Ulcerations of vaginal mucosa, if the lining of the vagina was already damaged before treatment;
- Uterine bleeding;
- Vaginal redness, vaginal dryness;
- Inflammation of the bladder (cystitis);
- Allergic reaction with symptoms like rash, swelling or itching;
- Fever.

Reporting of side effects

If you get any side effects, talk to your doctor. 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 FLUOMIZIN

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

Do not use Fluomizin after the expiry date which is stated on the carton and the blister. 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 Fluomizin contains

- The active substance is dequalinium chloride.
- Each vaginal tablet contains 10 mg dequalinium chloride.
- The other ingredients are lactose monohydrate, cellulose, microcrystalline and magnesium stearate.

What Fluomizin looks like and contents of the pack

Fluomizin vaginal tablets are white or almost white, oval and biconvex with approximate dimension of length: 19 mm, width: 12 mm, and thickness: 6.3 mm.

The vaginal tablets are available in packs containing a blister of 6 tablets.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

<to be completed nationally>

Manufacturer:

[To be completed nationally]

This medicinal product is authorised in the Member States of the EEA under the following names:

Member State-	Medicinal Product Name
Germany	- Fluomizin 10 mg Vaginaltabletten
The Czech Republic	- Naxyl 10 mg vaginální tablety
Belgium	- Fluomizin 10 mg tabletten voor vaginaal gebruik - Fluomizin 10 mg comprimés vaginaux - Fluomizin 10 mg Vaginaltabletten
Italy	- Fluomizin 10 mg compresse vaginali
Luxemburg	- Fluomizin 10 mg comprimés vaginaux
Austria	- Fluomizin 10 mg Vaginaltabletten
Poland	- Fluomizin 10 mg tabletki dopochwowe
Portugal	- Fluomizin 10 mg comprimidos vaginais
Slovakia	- Fluomizin 10 mg vaginálne tablety
Spain	- Fluomizin 10 mg comprimidos vaginales
Finland	- Donaxyl 10 mg emötinpuikko, tabletti
Hungary	- Fluomizin 10 mg hüvelytabletta
The Netherlands	- Fluomizin 10 mg tabletten voor vaginaal gebruik
Norway	- Donaxyl 10 mg vaginaltabletter
Sweden	- Donaxyl 10 mg vaginaltabletter

The United Kingdom - Fluomizin 10 mg vaginal tablets

This leaflet was last revised in {month YYYY}