

Patient Information Leaflet

FLUOMIZIN®

Dequalinium chloride 10 mg vaginal tablets

Read this leaflet carefully before you start taking this medicine because it contains important information for you. If you have questions or if you notice side effects not mentioned in this leaflet, contact your doctor or pharmacist. Do not pass this medicine on to others.

1. What Fluomizin is and what it is used for

Fluomizin is a vaginal tablet which dissolves in the vagina's natural moisture and releases the active substance, dequalinium chloride. Dequalinium chloride belongs to the group of anti-infective and antiseptic medicinal products (ATC code: G01AC05). This medicine is indicated for the treatment of vaginal infections caused by bacteria or fungi (e.g. bacterial vaginosis or candidiasis). Vaginal tablets are only active in the vagina and are not absorbed by the body.

2. What you need to know before you use Fluomizin

Do not take Fluomizin

- If you are allergic (hypersensitive) to dequalinium chloride or to any other ingredient of this medicine listed in section 6;
- If you have ulcers of the vagina or in the neck of the uterus;
- If you have not yet had your first menstrual period.

Warnings and precautions

- Do not use Fluomizin in the 12 hours before delivery.
- Avoid using soap or spermicides on your genitals and washing inside the vagina during treatment.
- Avoid sexual intercourse while using Fluomizin. Use a latex condom or another alternative method for at least 12 hours after treatment, since Fluomizin can affect condoms made of materials other than latex.
- There is insufficient experience with the use of Fluomizin in women over 55 years of age.

Children and adolescents

- There is insufficient experience with the use of Fluomizin in children and adolescents under 18 years of age.

Other medicines and Fluomizin

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

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, if you think you might be pregnant, or are planning to get pregnant, you must tell your doctor that you are taking medicines.

Driving and using machines

Fluomizin is not expected to affect your ability to drive or use machines.

3. How to use Fluomizin

Always use Fluomizin exactly as your doctor or pharmacist has told you.

- Insert one Fluomizin vaginal tablet in the vagina in the evening, for 6 days. Wash your hands before opening the blister. Insert the vaginal tablet deeply in the vagina before you go to bed. The easiest way to do this is, if you lie down with your legs drawn up.
- Although relief of vaginal discharge and inflammation generally occurs within 24 to 72 hours, the treatment should be continued even when there is no discomfort (itching, discharge, unpleasant odour) anymore.
- The treatment should be interrupted during menstruation and resumed afterwards.
- Sometimes the vaginal tablet does not dissolve completely in the vagina and deposits are found in the underwear. This does not affect the effectiveness of the treatment, nor will it give discoloration of your underwear.
- In case of vaginal dryness, the tablet may not dissolve and is expelled completely intact. In this case, it is recommended that the vaginal tablet is moistened with a few drops of water before being inserted deeply into the vagina.

If you use more Fluomizin than you should

A too high a dose could cause vaginal ulcers.

If you stop using Fluomizin

Treatment lasting under six days could result in a relapse. Do not interrupt the treatment prematurely, even if you no longer experience any symptoms or discomfort.

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

4. Possible side effects

Like all medicines, Fluomizin can cause side effects, although not everybody gets them.

Sometimes symptoms of vaginal infection (itching, burning sensation, discharge) may intensify at the beginning of the treatment, before improving. Complete the treatment with Fluomizin and if the problem persists after treatment, consult your doctor as soon as possible.

- Common side effects (more than 1 in 100 patients): vaginal discharge, stinging or itching pain, and vaginal fungal infections.
- Uncommon side effects (less than 1 in 100 patients): vaginal bleeding, vulvovaginal burning sensation, skin fungal infections, headache, nausea.
- Side effects of unknown frequency: vaginal ulceration and aggravated inflammation, uterine bleeding, redness, vaginal dryness, bladder inflammation, fever, allergic reactions at the application site.

If you notice any side effects, please tell your doctor, pharmacist or healthcare provider.

5. How to store Fluomizin

Keep out of the reach and sight of children.

Store below 30°C, in the original package.

Do not use this medicine after the expiry date, stated on the packaging (Exp.). The expiry date refers to the last day of that month.

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

6. Contents of the pack and further information

What Fluomizin contains

The active substance is dequalinium chloride.

The other ingredients are lactose monohydrate, microcrystalline cellulose, and magnesium stearate.

What Fluomizin looks like and content of the pack

White to almost white, oval, biconvex tablet.

Fluomizin is packaged in a box containing a blister with 6 tablets.

Fluomizin is a prescription medicine.

Manufacturer

Batch release: Medinova AG Eggbühlstrasse 28 CH-8050 Zürich, Switzerland

Manufacturing site: Rottendorf Pharma GmbH, Ostfelder Str. 51-61, 59320 Ennigerloh, Germany

Marketing Authorisation Holder

Dafra Pharma GmbH, Mühlenberg 7, 4052 Basel, Switzerland.

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