

Fluomizin® Vaginal Tablets

This is a medicament

Medicament is a product which affects your health and its use contrary to instructions is dangerous for you. Follow strictly the doctor's prescription, the method of use and the instruction of the pharmacist who sold the medicament.

- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

What is Fluomizin and when is it used?

Medicinal product on prescription only.

Fluomizin contains the active substance dequalinium chloride, which has anti-infective and antiseptic (disinfecting) properties. After insertion into the vagina, the vaginal tablet dissolves and releases the active substance. Dequalinium chloride is effective against numerous pathogens responsible for vaginal infections such as certain bacteria and fungi (Candida). Fluomizin vaginal tablets exert their action locally within the vagina and are used to treat bacterial and fungal infections. Marked relief with regard to discharge and inflammation generally occurs within 24 to 72 hours.

What should be considered before use?

This medicinal product has been prescribed for you by your doctor to treat your current disorder. Use of the wrong medication or administration of incorrect doses can cause complications. Therefore, it should not be used to treat any other condition or passed on to any other person. Even in the case of future recurrent infections, you should not use Fluomizin without consulting your doctor.

When must Fluomizin not be used?

Do not use Fluomizin if:

- you have an ulceration of the vaginal epithelium or the neck of the uterus;
- you are hypersensitive to the active substance or to one of the other ingredients
- you did not yet have your first menstruation.

When is caution advised during the use of Fluomizin?

If used as prescribed, no special care has to be taken.

Fluomizin does not interfere with the functionality of latex condoms. There are no studies available on the compatibility of the preparation with latex-free condoms or diaphragms, etc. Therefore, concomitant use of latex-free condoms and diaphragms with Fluomizin should be avoided for at least 12 hours after administration of the vaginal tablets.

Fluomizin is incompatible with soap and other anionic surfactants. Fluomizin must not be used at other parts of the body.

Inform your doctor or pharmacist if you

- are suffering from other disorders,
- have allergies or
- are taking or externally using other medicinal products (including non-prescription (over-the-counter) medicines).

Can Fluomizin be used during pregnancy and lactation?

Based on the present experience, there is no evidence for a risk to the unborn child provided that the medicinal product is used as prescribed. If you are pregnant or are breast-feeding your baby, you should avoid taking any medicine as a precautionary measure or consult your doctor or pharmacist.

How do you use Fluomizin?

Adults and adolescents after the first menstruation: Unless otherwise prescribed by your doctor, insert 1 vaginal tablet for 6 days deeply into the vagina in the evening before retiring as follows:

- Wash your hands thoroughly



- Lie on your back and keep your knees bent
- Insert the vaginal tablet deep into the vagina.

Treatment should be interrupted during menstruation and resumed afterwards.



Fluomizin contains ingredients that do not completely dissolve, such that remains of the tablet are found in the panties. This does not, however, impair the efficacy of the medicinal product.

In the rare cases of a very dry vagina, it is possible that the vaginal tablet does not dissolve and is discharged by the vagina as intact tablet. The vaginal tablet can be moistened with a drop of water before insertion into a very dry vagina. Use a panty-liner or sanitary towel.

There is no change in colour of the underwear. Underwear, towels and annels should be changed daily and laundered at a minimum temperature of 60°C. If you forget to take Fluomizin, do not take a double dose to make up for the missed dose, but continue treatment with 1 vaginal tablet per day.

A treatment of less than 6 days may result in a relapse. The discomfort may often disappear before the infection is completely cured. Therefore, do not stop treatment early, even when you have no discomfort (e.g. itching, discharge, smell) anymore.

Application of more than 1 vaginal tablet will not increase the efficacy of Fluomizin. This will rather result in an increase of side effects.

Always use Fluomizin exactly as your doctor has instructed you. If you have the impression that the effect of the medicinal product is too strong or too weak, talk to your doctor or pharmacist.

What possible side effects can Fluomizin have?

The following side effects may occur during the use of Fluomizin:

Vaginal infections cause generally complaints such as itching, burning and discharge. These complaints disappear usually during treatment.

Some of the side effects mentioned may also be symptoms of vaginal infection. In these cases it is not necessary to stop the treatment. However, if the complaints persist or increase, see your doctor for advice as soon as possible.

Common (affects 1 to 10 users in 100):

Vaginal discharge, itching, burning

Uncommon (affects 1 to 10 users in 1000):

Inflammation of the bladder, inflammation of the pubic area and vagina, fungal skin infection, genital herpes, headache, nausea, vaginal bleeding, vaginal redness, vaginal pain, fever, allergic reactions (e.g. skin rash, itching, redness), damage to the vaginal mucosa

Rare (affects 1 to 10 users in 10,000):

Vaginal dryness, other vaginal discomfort

Not known:

abdominal pain, vomiting, diarrhea. If fever occurs, treatment with Fluomizin should be discontinued

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Other points to note

Shelf life

Do not use the medicinal product after the expiry date indicated by „EXP“ on the package.

Storage

Do not store above 30°C. Fluomizin must be stored in the original package. Keep out of the reach and sight of children.

Further information

Further information may be obtained from your doctor or pharmacist who will have more detailed product information

What does Fluomizin contain?

1 vaginal tablet contains:

Active substance: Dequalinium chloride 10.0 mg The other excipients are lactose monohydrate, cellulose microcrystalline and magnesium stearate per tablet.

Where do you obtain Fluomizin? What pack sizes are available?

Fluomizin is available from pharmacies only on prescription. Packs of 6 vaginal tablets.

Manufactured by:

Rottendorf Pharma GmbH
Ostenfelder Strasse 51-61
59320 Ennigerloh
Germany

For:

 medinova

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