

FLUOMIZIN[®] VAGINAL TABLETS

Dequalinium chloride (10mg)

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What Fluomizin[®] vaginal tablets are used for

Fluomizin[®] vaginal tablets is used for treatment of vaginal infections, which caused by bacteria (bacterial vaginosis), yeast (Candida infections) and parasite (trichomoniasis). It is also used for preparation of aseptic condition before gynecological operation or deliveries.

How Fluomizin[®] vaginal tablets work

After insertion into the vagina, Fluomizin[®] vaginal tablets dissolve and release the active substance dequalinium chloride. Dequalinium chloride effective against a wide range of bacteria, fungi (yeasts) and protozoa (Trichomonas), which can be the cause of vaginal infections.

Fluomizin[®] vaginal tablets acts locally within the vagina. Marked relief of discharge and inflammation generally occurs within 24 to 72 hours.

Before you use Fluomizin[®] vaginal tablets

-When you must not use it

You must not use Fluomizin[®] vaginal tablets if you have:

- Hypersensitivity to the ingredients listed in Product Description
- Ulceration of the vaginal lining or neck of the uterus
- not yet reached sexual maturity (young girls should not use this preparation)

-Before you start to use it

Please tell your doctor or pharmacist if you are allergic to any medicines, food, preservatives or dye.

During pregnancy and breastfeeding, Fluomizin[®] vaginal tablets can be used after consulting a medical doctor or pharmacist.

However, as in general, caution should be exercised when using Fluomizin by pregnant women in the first trimester.

-Taking other medicines

You should inform the doctor or pharmacist if you are using or have recently used any other medicines, even those not prescribed.

How to use Fluomizin[®] vaginal tablets

-How much to use

If not otherwise instructed by your doctor or pharmacist, follow the directions below.

The usual dose is one vaginal tablet daily.

-When to use it

The vaginal tablets should be inserted deeply into the vagina in the evenings before retiring. This is best performed in a reclining position with the legs slightly bent.

Treatment should be interrupted during menstruation and resumed afterwards.

-How long to use it

Usually for six consecutive days.

The treatment should be continued even when there is no discomfort such as itching, discharge and smell anymore. A treatment of less than six days could result in a relapse.

-If you forget to use it

Do not take a double dose to compensate the forgotten dose. Just take the next dose at the usual time.

-If you use too much (overdose)

Contact your doctor or pharmacist if this occurs. Application of more than 1 vaginal tablet will not increase the efficacy of Fluomizin[®] vaginal tablets. This could rather result in an increase of undesirable effects.

While you are using Fluomizin[®] vaginal tablets

-Things you must do

Use your medicine exactly as your doctor has told you.

Tell your doctor if you become pregnant while using this medication.

Fluomizin[®] vaginal tablets contain excipients which do not dissolve completely, such that remains of the tablet could occasionally be found in the

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panties. This is of no importance for the efficacy of Fluomizin[®] vaginal tablets. In 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. As consequence, the treatment is not optimal. However, this is not harmful to the vagina. For prevention, the vaginal tablet can be moistened with a drop of water before insertion into a very dry vagina.

-Things you must not do

You should not use vaginal douches or rinses during treatment with Fluomizin[®] vaginal tablets.

Do not stop using the medicine unless advised by your doctor or pharmacist.

Do not use any new medicine without consulting your doctor.

Do not give Fluomizin[®] vaginal tablets to anyone else, even if they have the same symptoms or condition as you.

-Things to be careful of

You should use a sanitary towel or panty liner. There is no change in the colour of the underwear. Please change your underwear and flannel daily and launder them at a temperature of at least 80 °C.

Side effects

Like all medicines, Fluomizin[®] can possibly cause side effects, although not everybody gets them.

The following side effects have been observed rarely after usage of Fluomizin[®] vaginal tablets: itchiness, burning, redness. Treatment should be continued. However, you should consult your doctor if symptoms persist.

In individual cases, where the vaginal surface was predamaged, e.g. as a consequence of an estrogen deficit or distinct inflammation, bleeding surface defects in the vagina have been reported. In case of unexpected bleeding, you should stop using the medication and consult your doctor.

In individual cases, fever has been reported.

Based on the experience with Fluomizin[®] vaginal tablets during pregnancy, there is no evidence for adverse effects on pregnancy or on the health of the foetus /new-born child.

If you notice any side effects becoming more serious or is not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website np.ra.moh.gov.my (Public → Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety).

Storage and Disposal of Fluomizin[®] vaginal tablets

-Storage

Keep out of the reach and sight of children.

Do not use your medicine after the expiry date stated on the packaging.

Do not store above 30°C.

-Disposal

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.

Product description

-What it looks like

The vaginal tablets are white or almost white, oval and biconvex.

-Ingredients

- Active ingredients : dequalinium chloride
- Inactive ingredients : Lactose monohydrate, Cellulose microcrystalline, Magnesium stearate

-MAL number

MAL08032208XCS

Manufacturer

Rottendorf Pharma GmbH
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Product Registration Holder

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