**SCHEDULING STATUS: S2**

# FLUOMIZIN®, 10 mg vaginal tablet
## Dequalinium chloride

**Read all of this leaflet carefully because it contains important information for you**
FLUOMIZIN is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use FLUOMIZIN carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share FLUOMIZIN with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 6 days.

**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
Fluomizin is for vaginal use. Do not swallow.
Dequalinium chloride is active against the bacteria which cause bacterial vaginosis. It acts by either slowing down or stopping the growth of the germs or spread of an infection or killing the germ that caused the infection.
FLUOMIZIN is used for the treatment of vaginal infections of bacterial origin.

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 hypersensitive (allergic) to dequalinium chloride or to any of the other ingredients of FLUOMIZIN (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**
Special care should be taken with FLUOMIZIN:
- Do not use FLUOMIZIN within 12 hours before birth to minimise exposure of the newborn to dequalinium chloride. Please inform your doctor otherwise.
- You should talk to your doctor if the symptoms persist at the end of the treatment or in case the symptoms return.
- Using a higher daily dose or increasing the recommended treatment duration might increase the risk of vaginal ulcerations.
- Unprotected sexual intercourse during treatment with FLUOMIZIN is not recommend.
- FLUOMIZIN does not reduce the effectiveness of latex condoms.
- FLUOMIZIN may reduce the effectiveness of non-latex condoms or diaphragms. Consequently, you should use alternative methods of contraceptive for at least 12 hours following treatment.

**Children and adolescents**
There is no data to support the use of the use of FLUOMIZIN in children and adolescents under 18 years of age.

**Women above 55 years and elderly**
There is no data to support the use of the use of FLUOMIZIN in women above 55 years.

**Other medicines and FLUOMIZIN**
Always tell your healthcare provider if you are taking any other medicine.
(This includes all complementary or traditional medicines.)

Do not use intravaginal soaps, spermicides and vaginal douches (vaginal washes) during treatment with FLUOMIZIN.

There is no data on the interaction with non-latex condoms and other intravaginal devices such as diaphragms. Consequently, you should use alternative methods of contraception for at least 12 hours following the treatment.

**Pregnancy and breastfeeding and fertility**
If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before using FLUOMIZIN.

**Driving and using machines**
FLUOMIZIN is not likely to affect your ability to drive or operate any machinery. No studies have been performed.

It is not always possible to predict to what extent FLUOMIZIN may interfere with your daily activities. You should ensure that you do not engage in driving a vehicle or use machines until you are aware of the measure to which FLUOMIZIN affects you.

**3. How to use FLUOMIZIN**
Do not share medicines prescribed for you with any other person.

Always use FLUOMIZIN exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse 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 will not 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 an intact tablet. As a consequence, the treatment is not optimal. In this case the vaginal tablet can be moistened with a drop of clean water before insertion.

**Children and adolescents up to 18 years and over 55 years of age**

The safety and efficacy of FLUOMIZIN have not been established.

**If you use more FLUOMIZIN than you should**
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

**If you forget to use FLUOMIZIN**
Do not insert a double dose to make up for forgotten individual doses.

**4. Possible side effects**
FLUOMIZIN can have side effects.
Not all side effects reported for FLUOMIZIN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using FLUOMIZIN, please consult your healthcare provider for advice.

If any of the following happens, stop using FLUOMIZIN and tell your doctor immediately or go to the casualty department at your nearest hospital:
- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching.

These are all very serious side effects. If you have them, you may have had a serious reaction to FLUOMIZIN. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:
*Frequent side effects:*
- vaginal yeast infection (thrush)
- vaginal discharge; vaginal itching or vaginal burning

*Less frequent side effects:*
- inflammation of the vagina (vaginitis) due to the overgrowth of bacteria
- inflammation of the vagina (vaginitis) and vulva (vulvitis) or both (vulvo-vaginitis)
- fungal skin infections
- headache
- nausea
- vaginal bleeding
- vaginal pain

*Side effects with unknown frequency:*
- inflammation of the bladder (cystitis)
- ulcerations of vaginal mucosa, if the lining of the vagina was already damaged before treatment
- uterine bleeding
- vaginal redness
- vaginal dryness
- a skin rash accompanying a disease or fever
- hives, redness of the skin, swelling

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

**Reporting of side effects**
If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of FLUOMIZIN.

**5. How to store FLUOMIZIN**
STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
Store at or below 30 °C.
Store in the original packaging. Do not remove the blister from the carton until required for use.
Do not use FLUOMIZIN after the expiry date which is stated on the carton after "EXP". The expiry date refers to the last day of that month.
Return all unused medicine to your pharmacist.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

**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 microcrystalline cellulose, lactose monohydrate, magnesium stearate.

**What FLUOMIZIN looks like and contents of the pack**
FLUOMIZIN vaginal tablets are white or almost white, oval, biconvex tablets.

FLUOMIZIN vaginal tablets are packed in blisters which consists of a polymer film (PVC/PE/PVdC) with an aluminium push through foil.
FLUOMIZIN vaginal tablets are packed in units of 6 vaginal tablets per blister.
One blister of FLUOMIZIN vaginal tablets is packed into a carton box.

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