Summary of Product Characteristics for Pharmaceutical Products

1. Name of the medicinal product

Fluomizin 10 mg vaginal tablets

2. Qualitative and quantitative composition

Each vaginal tablet contains 10 mg dequalinium chloride.
For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Vaginal tablet
White or almost white, oval, biconvex tablet.

4. Clinical particulars

4.1 Therapeutic indications

Fluomizin 10 mg vaginal tablets are indicated for the treatment of vaginal infections of bacterial and mycotic origin (e.g. bacterial vaginosis and candidiasis).
Consideration should be given to official guidance on the appropriate use of antibacterial agents.

4.2 Posology and method of administration

Posology

One vaginal tablet daily for six days.
The treatment should best be interrupted during menstruation and resumed afterwards.
Although relief of discharge and inflammation generally occurs within 24 to 72 hours, the treatment should be continued even when there is no subjective discomfort (itching, discharge, smell) anymore. A treatment less than six days could result in a relapse.
Fluomizin contains excipients that do not dissolve entirely. It is therefore possible that remains of the tablet will emerge from the vagina. Remains of the tablet are occasionally found in the underwear. However, this does not alter the effectiveness of the medicine.

Special populations

Women aged more than 55 years

There are insufficient efficacy and safety data for use of dequalinium chloride in women aged more than 55 years.

Pediatric population

There are insufficient efficacy and safety data for use of dequalinium chloride in children under 18 years of age. There is no relevant indication for use of Fluomizin in children.

Method of administration

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

In very rare cases of extreme dryness of the vagina, the vaginal tablet may not dissolve completely and may emerge from the vagina. There is no risk of vaginal injury. The vaginal tablet can be moistened with a drop of water before being introduced into a very dry vagina.
Patients should be recommended using a sanitary towel or panty liner. There is no change of colour of the underwear. Patients should be instructed to change their underwear and flannel daily and launder them at high temperature.

4.3 Contraindications

- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
- Ulceration of the vaginal epithelium and the vaginal portion of the cervix.
- Young girls who have not yet had their first menstruation, and thus did not reach sexual maturity must not use Fluomizin.

4.4 Special warnings and precautions for use

General information

- Using a higher daily dose or increasing the recommended treatment duration might increase the risk of vaginal ulcerations.
- There are no data available on the efficacy and safety of the renewal of treatment for patients who did not respond to initial treatment with Fluomizin or who relapsed immediately after treatment. Patients should be advised to consult their doctor if symptoms persist or reoccur at the end of treatment.
- There are no efficacy and safety data available on the treatment of bacterial vaginoses in women aged less than 18 years and more than 55 years.
- To minimize the exposure of the new-born to dequalinium chloride, vaginal tablets should not be used within 12 hours prior to delivery.

Pediatric population

There are insufficient efficacy and safety data for use of dequalinium chloride in children under 18 years of age.

4.5 Interaction with other medicinal products and other forms of interaction.

- Anionic substances such as soaps, detergents and surfactants can reduce the antimicrobial activity of dequalinium chloride. Therefore, the concomitant intravaginal use of soaps, spermicides and vaginal irrigation (washes) should be discouraged.
- Fluomizin vaginal tablets do not impair the functionality of latex condoms. There are no data on the interaction with non-latex condoms and other intravaginal devices such as diaphragms. Therefore, concomitant use of non-latex condoms and other intravaginal devices is discouraged for at least 12 hours after treatment.

4.6 Pregnancy and Lactation

Fertility

No reproductive toxicity studies have been conducted in animals because of the expected low systemic exposure to dequalinium chloride after vaginal administration.

Pregnancy

Four clinical studies involving 181 pregnant patients did not demonstrate any adverse effect on the pregnancy or on the foetus or the new-born. Furthermore, considerable post-marketing experience of Fluomizin indicates the absence of malformities or foetal/neonatal toxicity. The use of Fluomizin may be considered during pregnancy, if necessary.

Lactation

Systemic exposure of the breast-feeding women to dequalinium chloride is negligible. Therefore, no harmful effects on the breasted new born/infant are anticipated. Fluomizin can be used during lactation if clinically needed.

To minimize the exposure of the new-born to dequalinium chloride, vaginal tablets should not be used within 12 hours prior to delivery.

4.7 Effects on ability to drive and use machines

No studies on the effect on the ability to drive and use of machines have been performed. However, given the low systemic availability such influence is unlikely.

4.8 Undesirable effects

Summary of the safety profile

The undesirable effects have been reported during clinical trials and during postmarketing monitoring.

Tabulated summary of adverse reaction

Some of the symptoms mentioned (such as pruritus, burning sensations or Fluor vaginalis) can also be symptoms of the vaginal infection. In this case, it is not necessary to interrupt the treatment.

System organ class	**Common ≥ 1/100 to**	**Uncommon ≥ 1/1000 to**	**Frequency not known (cannot be estimated from available data)1**
Infections and infestation	-vaginal candidiasis	-bacterial vaginitis -fungal skin infection -vulvitis -vulvovaginitis	-cystitis
Nervous system disorders		-headache	
Gastrointestinal disorders		-nausea	

Reproductive system and breast disorders	-vaginal discharge -vulvovaginal pruritis -vulvovaginal burning sensation	-vaginal haemorrhage -vaginal pain	-ulceration and maceration of vaginal epithelium -uterine bleeding -redness -vaginal dryness
General disorders and administration site conditions			-allergic reactions (manifested by symptoms such as hives, erythema, exanthema, edema, rash -fever

4.9 Overdose

No case of overdose has been reported. However, use of a higher daily dose might result in vaginal ulcerations. Also, there are no expected adverse effects in case of accidental ingestion of Fluomizin. However, a few cases of nausea, abdominal pain, vomiting and diarrhea have been reported.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Gynaecological anti-infective and antiseptic, Quinoline derivatives, ATC code: G01A C05.

Dequalinium chloride is an anti-infective and antiseptic agent belonging to the class of quaternary ammonium compound.

Mode of action

Dequalinium chloride is a surface-active substance. The primary mode of action is an increase in bacterial cell permeability and the subsequent loss of enzyme activity, finally resulting in cell-death.
Dequalinium chloride exhibits a rapid bactericidal and fungicidal activity.
Dequalinium chloride in vaginal tablets exerts its action locally within the vagina.

Pharmacokinetic/pharmacodynamics relationship

No major PK/PD determinant of efficacy has been established for Fluomizin. As the bactericidal effect of dequalinium chloride occurs within 30 to 60 minutes, the maximum local concentration within the first hour after application is considered crucial for the efficacy.

Mechanism(s) of resistance

The mechanisms resulting in the inherent resistance of some pathogens are not known. No mechanisms of acquired resistance have been observed thus far.

Breakpoints
No Breakpoints for dequalinium chloride are available by any recommending body and no relationship between minimal inhibitory concentrations and the clinical efficacy has been established. Thus, the information on susceptibility in the table below is descriptive and is based on the concentrations achievable in the vagina (see section 5.2) and respective MIC data of the pathogens.
The prevalence of acquired resistance may vary geographically and with time for selected species and local information on resistance is desirable, particularly when treating severe infections. As necessary, expert advice should be sought when the local prevalence of resistance is such that the utility of the agent in at least some types of infection is questionable.

Commonly susceptible species

Aerobic Gram-positive bacteria
Enterococcus faecalis
Lactobacillus spp.
Staphylococcus aureus
Streptococcus agalactiae (Group B streptococci)
Streptococcus pyogenes (Group A streptococci)

Aerobic Gram-negative bacteria
Enterobacter spp.
Escherichia coli
Klebsiella spp.
Pseudomonas spp.
Serratia spp.

Anaerobic bacteria
Atopobium vaginae
Bacteroides spp
Fusobacteria
Gardnerella vaginalis
Prevotella spp.
Peptostreptococci
Poryphyromonas spp

Fungi
Candida albicans
Candida tropicalis
Candida glabrata
Candida Krusei

Species for which acquired resistance may be a problem
None known

Inherently resistant organisms

Gram-negative bacteria
Proteus sp.
Chlamydia trachomatis

Other micro-organisms
Trichomonas vaginalis

5.2 Pharmacokinetic properties

After dissolution of a Fluomizin vaginal tablet (10 mg dequalinum chloride) in an estimated 2.5 to 5 ml of vaginal fluid, the dequalinium chloride concentration in the vaginal fluid is 2000-4000 mg/l, which is higher than the MIC90 of all tested pathogenic microorganisms.

Preclinical data indicate that dequalinium chloride is absorbed only to a very small amount after vaginal application.
Therefore, systemic exposure to Fluomizin is negligible and no further pharmacokinetic data are available.

5.3 Preclinical safety data

Systemic toxic effects of Fluomizin are unlikely on the basis of the negligible systemic exposure of dequalinium chloride administered intravaginally.
In vivo and in vitro studies with dequalinium chloride did not yield any indication of a potential to cause mutagenicity.
No reproduction toxicity studies have been conducted with dequalinium chloride.
A study in rabbits showed the good vaginal tolerance of Fluomizin.

6. Pharmaceutical Particulars

6.1 List of Excipients

Lactose monohydrate
Microcrystalline cellulose (E460a)
Magnesium stearate (E470b)

6.2 Incompatibilities

Fluomizin is incompatible with soaps and other anionic surfactants.

6.3 Shelf-Life

3 years

6.4 Special Precautions for storage

Store below 30°C.
Store in the original package.

6.5 Nature and Content of container

PVC/PE/PVdC -aluminium blister.
Box containing 6 vaginal tablets (1x6).

6.6 Special precautions for disposal and other handling

No special requirements for disposal.

Any unused product or waste material should be disposed of in accordance with local requirements.

7. Marketing Authorization Holder

Dafra Pharma GmbH,
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8. Marketing Authorization Number

CTD8606

9. Date of first authorization/renewal of the authorization

25/05/2023

10. Date of revision of the text

07/05/2025