

Fluomizin[®]

dequalinium chloride

PREVENTION AND TREATMENT OF VAGINAL INFECTIONS
OF BACTERIAL AND MYCOTIC ORIGIN

POSODOLOGY

Route of administration: vaginal insertion

Vaginal tablet

Once daily for six days
Introduce a vaginal tablet deeply into
the vagina every night before bed.

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, odour) anymore. A treatment less than six days could result in a relapse. There is no relevant indication for use of **FLUOMIZIN[®]** in children.

ADVANTAGES AND KEY POINTS:

Broad spectrum, specific action
Long-term efficacy
No known resistance
Local application, good tolerance
Can be used during pregnancy and lactation

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Setting the Standard
www.dafrapharma.com

Fluomizin[®]

dequalinium chloride



ANTIMICROBIAL ACTIVITY
AGAINST ALL MAJOR PATHOGENS RESPONSIBLE
FOR VAGINAL INFECTIONS

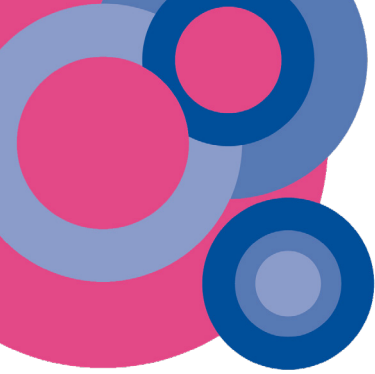
Rapid disappearance of itching, discharge and odour

BROAD SPECTRUM - SPECIFIC ACTION



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 medinova

PRESENTATION

Box of 6 vaginal tablets. Each tablet contains 10 mg dequalinium chloride.

INDICATIONS

Vaginal infections of bacterial and mycotic origin (e.g. bacterial vaginosis and candidiasis); achievement of asepsis before gynecological operations and deliveries.

POSODOLOGY AND METHOD OF ADMINISTRATION

Route of administration: vaginal use. One vaginal tablet daily for six days. The vaginal tablets should be inserted deeply into the vagina in the evenings before bed. This is best performed in a reclining position with the legs slightly bent. 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. There is no relevant indication for use of **FLUOMIZIN[®]** in children.

CONTRA-INDICATIONS

Hypersensitivity to the active substance or to any of the excipients. Ulceration of the vaginal epithelium and portio vaginalis uteri. Young girls who have not yet had their first menstruation, and thus did not reach sexual maturity must not use **FLUOMIZIN[®]**.

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. Thus, concomitant intra vaginal use of soaps, spermicides or vaginal douches (vaginal washes) is not recommended. **FLUOMIZIN[®]** 10 mg vaginal tablets do not impair the functionality of latex condoms. There are no data on the interaction with non-latex condoms and other intra vaginal devices such as diaphragms. Thus, concomitant use of non-latex condoms and other intra vaginal devices is not recommended.

PREGNANCY AND LACTATION

FLUOMIZIN[®] can be used during pregnancy and lactation. Four clinical studies involving 181 pregnant patients did not demonstrate any adverse effect on the pregnancy or on the fetus/neonate. Furthermore, considerable post-marketing experience indicates no malformative or feto/neonatal toxicity of **FLUOMIZIN[®]**. No reproductive toxicity studies have been conducted in animals because of the expected low systemic exposure to dequalinium chloride after vaginal administration. Lactation: Systemic exposure of the breast-feeding women to **FLUOMIZIN[®]** is negligible. Therefore, no harmful effects on the breastfed newborn/infant are anticipated.

UNDESIRABLE EFFECTS

In clinical trials, the following undesirable effects possibly or probably related to dequalinium chloride have been reported. Within each frequency grouping, undesirable effects are presented in order of decreasing

SYSTEM ORGAN CLASS	COMMON (≥1/100 TO <1/10)	UNCOMMON (>1/1000 At <1/100)
Reproductive system and breast disorders	Vaginal discharge, vulvovaginal pruritus, vulvovaginal burning sensation	Vaginal haemorrhage, vaginal pain
Infections and infestations	Vaginal candidiasis	Bacterial vaginitis, fungal skin, infection, vulvitis, vulvovaginitis
Nervous system disorder		Headache
Gastrointestinal disorders		Nausea

seriousness. During post-marketing experience the following undesirable effects have been reported (frequency unknown): Reproductive system and breast disorders: ulceration and maceration of vaginal epithelium, uterine bleeding, redness, vaginal dryness; infections and infestations: cystitis; general disorders and administration site conditions: fever, allergic reactions.

PHARMACODYNAMIC PROPERTIES

Pharmacotherapeutic group: Gynecological anti-infective and antiseptic. ATC code: G01A C05. **FLUOMIZIN®** contains dequalinium chloride, a quaternary ammonium compound with a broad antimicrobial spectrum against different Gram-positive and Gram-negative bacteria, fungi, and protozoa (*Trichomonas vaginalis*). 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. Marked relief of discharge and inflammation generally occurs within 24 to 72 hours. PK/PD 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 and respective MIC data of the pathogens. Antimicrobial spectrum: Commonly susceptible species: Aerobic Gram-positive bacteria (*Enterococcus faecalis* *Lactobacillus* spp., *Listeria* 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*); inherently resistant organisms: Gram-negative bacteria (*Proteus* sp., *Chlamydia trachomatis*).

PHARMACOKINETIC PROPERTIES

After dissolution of a **FLUOMIZIN®** vaginal tablet (10 mg dequalinium chloride) in an estimated 2.5 to 5 ml of vaginal fluid, the dequalinium chloride concentration in the vaginal fluid is 4000 to 2000 mg/l, which is higher as the MIC90 of all tested pathogenic microorganisms. Preclinical data from rabbits indicate that dequalinium chloride is absorbed only to a very small amount after vaginal application. Therefore, systemic exposure to **FLUOMIZIN®** is negligible and not further pharmacokinetic data are available.

SPECIAL PRECAUTIONS FOR STORAGE

Store below 30°C in the original package. Keep out of reach and sight of children.

MANUFACTURER

Rottendorf Pharma GmbH, Ostenfelder Str. 51-61, 59320 Ennigerloh, Germany.

MARKETING AUTHORISATION HOLDER

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

		● Sensitive ● Partially sensitive ● Resistant ○ Absence of data							
		Substances	Fluomizin®	Clindamycin	Metronidazole	Hexetidine	Povidoniod	Clotrimazol	Fluconazol
Pathogens									
Bacteria	Anaerobic		●	●	●	●	●	●	●
	Gram Positive Aertobic		●	●	●	●	●	●	●
	Gram Negative Aerobic		●	●	●	●	●	●	●
Fungi	Candida albicans		●	●	●	●	●	●	●
	Candida glabrata Candida krusel		●	●	●	○	●	●	●

For the complete SMPC, please visit www.dafrapharma.com