

**South East London Integrated Medicines Optimisation Committee
(SEL IMOC, formerly the SEL Area Prescribing Committee)
Formulary recommendation**

Reference:	127
Intervention:	Dequalinium chloride 10 mg vaginal tablets (Fluomizin™) for the treatment of bacterial vaginosis (Dequalinium chloride is an antiseptic which causes bacterial cell death by increasing cell permeability and reducing enzyme activity)
Date of Decision:	September 2021
Date of Issue:	October 2021
Recommendation:	GREEN – can be prescribed within agreed criteria for use in primary or secondary care
Further Information:	<ul style="list-style-type: none"> Dequalinium chloride 10 mg vaginal tablets (Fluomizin™) is approved for use in SEL in line with its licensed indication – treatment of bacterial vaginosis. Dequalinium chloride 10 mg vaginal tablets (Fluomizin™) is reserved as a 2nd line, treatment option in patients with bacterial vaginosis where oral metronidazole has failed or is not well tolerated. Other second line treatment options include metronidazole vaginal gel or clindamycin vaginal cream. Information on the general management of bacterial vaginosis can be found in the Clinical Knowledge Summaries (CKS) entry. Dequalinium vaginal tablets should be inserted deeply into the vagina once daily at night for 6 days as a single treatment course. In line with the current Summary of Product Characteristics (SmPC) for dequalinium there is a lack of data on the efficacy and safety of dequalinium in women above 55 years of age, it is therefore recommended dequalinium is not prescribed in women above the age of 55. Treatment with dequalinium should be interrupted during menstruation and resumed afterwards. Dequalinium should not be used if there is known hypersensitivity to dequalinium or any of the excipients (lactose monohydrate, cellulose, microcrystalline and magnesium stearate). Dequalinium should also not be used if there is ulceration of the vaginal epithelium and the vaginal portion of the cervix. The current SmPC notes that limited data on the use of dequalinium in pregnancy did not suggest adverse effects on the pregnancy or on the foetus / neonate. Dequalinium should only be used in pregnancy if clearly necessary and only on the advice of a genitourinary medicine (GUM) consultant.
Shared Care/ Transfer of care required:	N/A
Cost Impact for agreed patient group	<ul style="list-style-type: none"> Based on the evidence review it is expected ~1,040 patients from SEL will be treated with dequalinium for the management of bacterial vaginosis per annum. Dequalinium vaginal tablets are £6.95 for the treatment course. This is less costly than clindamycin vaginal cream (£10.86) but more costly than metronidazole vaginal gel (£4.31). The introduction of dequalinium in SEL is therefore expected to be cost neutral.
Usage Monitoring & Impact Assessment	Acute Trusts/Community GUM clinics <ul style="list-style-type: none"> Monitor and submit usage and audit data on request to the SEL IMOC. Community sexual health services are commissioned by local authorities and Borough Medicines Optimisation leads should work with their LA leads to facilitate this process (see below)
	SEL CCG Borough Medicines Optimisation Teams: <ul style="list-style-type: none"> Monitor primary care prescribing data. Audit locally (including locally commissioned GUM services) to ensure use in line with this recommendation and the local pathway.

	<ul style="list-style-type: none"> • Exception reports from GPs if inappropriate prescribing requests are made to primary care.
Evidence reviewed	<p>References (from evidence evaluation)</p> <ol style="list-style-type: none"> 1. Weissenbacher ER et al, A Comparison of Dequalinium Chloride Vaginal Tablets (Fluomizin®) and Clindamycin Vaginal Cream in the Treatment of Bacterial Vaginosis: A Single-Blind Randomized Clinical Trial of Efficacy and Safety, <i>Gynecol Obstet Invest</i>; 2012; 73(1):8–15 2. GSTT guidance. The Management of vaginal discharge likely to be Bacterial Vaginosis (BV) June 2017 3. Guidelines for the management of Bacterial Vaginosis. BASHH 2012 http://www.bashh.org/documents/4413.pdf 4. Sobel JD, Schmitt C, Meriwether C. Long-term follow-up of patients with bacterial vaginosis treated with oral metronidazole and topical clindamycin. <i>J Infect Dis</i>. 1993 Mar;167(3):783–4. 5. Bradshaw CS, Morton AN, Hocking J, Garland SM, Morris MB, Moss LM, et al. High recurrence rates of bacterial vaginosis over the course of 12 months after oral metronidazole therapy and factors associated with recurrence. <i>J Infect Dis</i>. 2006 Jun 1;193(11):1478–86 6. Mendling W, Weissenbacher ER, Gerber S, Prasauskas V, Grob P. Use of locally delivered dequalinium chloride in the treatment of vaginal infections: a review. <i>Arch Gynecol Obstet</i>. 2016;293:469–84 7. Nagaraja P. Antibiotic resistance of Gardnerella vaginalis in recurrent bacterial vaginosis. <i>Indian J. Med Microbiol</i>. 2008 Jun;26(2):155–7. 8. Austin MN, Beigi RH, Meyn LA, Hillier SL. Microbiologic response to treatment of bacterial vaginosis with topical clindamycin or metronidazole. <i>J Clin Microbiol</i>. 2005 Sep;43(9):4492–7. 9. SPC Clindamycin cream 2%. 2014. 10. Meadowcroft AM, Diaz PR, Latham GS. Clostridium difficile toxin-induced colitis after use of clindamycin phosphate vaginal cream. <i>Ann Pharmacother</i>. 1998 Mar;32(3):309–11 11. Trexler MF, Fraser TG, Jones MP. Fulminant pseudomembranous colitis caused by clindamycin phosphate vaginal cream. <i>Am J Gastroenterol</i>. 1997 Nov;92(11):2112–3. 12. Slimings C, Riley TV. Antibiotics and hospital-acquired Clostridium difficile infection: update of systematic review and meta-analysis. <i>J Antimicrob Chemother</i>. 2014 Apr;69(4):881–91. 13. Spigaglia P. Recent advances in the understanding of antibiotic resistance in Clostridium difficile infection. <i>Ther Adv Infect Dis</i>. 2016 Feb;3(1):23–42. 14. Quality Premium: 2016/17 Guidance for CCGs. NHS; 2016 15. Jarrad AM, Karoli T, Blaskovich MAT, Lyras D, Cooper MA. Clostridium difficile drug pipeline challenges in discovery and development of new agents. <i>J Med Chem</i>. 2015 Jul 9;58(13):5164–85. 16. Adler A, Miller-Roll T, Bradenstein R, Block C, Mendelson B, Parizade M, et al. A national survey of the molecular epidemiology of Clostridium difficile in Israel: the dissemination of the ribotype 027 strain with reduced susceptibility to vancomycin and metronidazole. <i>Diagn Microbiol Infect Dis</i>. 2015 Sep;83(1):21–4. 17. Petersen EE, Weissenbacher ER, Hengst P, Spitzbart H, Weise W, Wolff F, Dreher E, Ernst U, Della Casa V, Pohlig G, Graf F, Kaiser RR. Local treatment of vaginal infections of varying etiology with dequalinium chloride or povidone iodine. A randomised, double-blind, active-controlled, multicentric clinical study. <i>Arzneimittelforschung</i> 2002;52:706-715. https://www.ncbi.nlm.nih.gov/pubmed/12404887 18. Grob P. Periodic Safety Update Report for Fluomizin / Donaxyl / Naxyl Vaginal Tablets (10mg Dequalinium Chloride). Zurich: Medinova AG; 2014 Jan. Report No.: PSUR #24. 19. Foulkes DM. Some toxicological observations on chlorhexidine. <i>J Periodontal Res Suppl</i>. 1973;12:55–60 20. Palmer AK, Bottomley AM, Edwards JA, Clark R. Absence of embryotoxic effects in rats with three quaternary ammonium compounds (cationic surfactants). <i>Toxicology</i>. 1983 Apr;26(3–4):313–5. 21. Summary of Product Characteristics. Fluomizin (10mg vaginal tablet). 2015. Date last accessed: 24/09/2021. Date of revision of the text: 11/04/2017. https://www.medicines.org.uk/emc/product/1997 22. Sherrard J, Donders G, White D, Jensen JS, European IUSTI. European (IUSTI/WHO) guideline on the management of vaginal discharge, 2011. <i>Int J STD AIDS</i>. 2011 Aug;22(8):421–9. 23. Mims online https://www.mims.co.uk/drugs/genito-urinary-system/genital-infections/zidoval

NOTES:

- a) SEL IMOC recommendations and minutes are available publicly via the [website](#).
- b) This SEL IMOC recommendation has been made on the cost effectiveness, patient outcome and safety data available at the time. The recommendation will be subject to review if new data becomes available, costs are higher than expected or new NICE guidelines or technology appraisals are issued.
- c) **Not to be used for commercial or marketing purposes. Strictly for use within the NHS.**