DORSET MEDICINES ADVISORY GROUP

COMMISSIONING STATEMENT ON THE USE OF THE LIDOCAINE AND PRILOCAINE SPRAY (FORTACIN® (EU); TEMPE®)

SUMMARY **The Dorset Medicines Advisory Group does not recommend the use of lidocaine and prilocaine spray (Fortacin® (EU); Tempe®) for premature ejaculation.**	
BACKGROUND	Lidocaine/Prilocaine (150 mg/ml + 50 mg/ml) spray is indicated for the treatment of primary premature ejaculation in adult men. In September 2013, the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) recommended the authorisation of Lidocaine/Prilocaine Plethora (lidocaine/prilocaine) for the treatment of premature ejaculation in adult men. Lidocaine/Prilocaine Plethora (also called PSD502, TEMPE) contains the active substances lidocaine and prilocaine, local anaesthetics that act by blocking the transmission of nerve impulses, reducing sensory stimulation. The medicine has been developed as a cutaneous spray solution able to provide rapid-onset topical anaesthesia to the glans penis mucosal surface for the treatment of primary premature ejaculation in adult men. The recommended dose is 3 actuations applied to cover the glans penis. Each such dose supplies a total of 22.5 mg lidocaine and 7.5 mg prilocaine. A maximum of 3 doses can be used within 24 hours with at least 4 hours between doses. Overall the CHMP concluded, the efficacy of lidocaine/prilocaine over placebo has been demonstrated. The adverse effect profile of lidocaine/prilocaine for both male subjects and their female partners appears to be benign and manageable and no new safety signals have been observed with lidocaine/prilocaine. Therefore the benefit/risk balance of lidocaine/prilocaine in the treatment of premature ejaculation in adult men is considered positive. In an ex-vivo study in rats, Lidocaine/Prilocaine Plethora was shown to reduce sperm motility and therefore the potential for reduction of sperm motility following clinical use of the medicinal product cannot be excluded.
RELEVANT NICE GUIDANCE	No NICE guidance available. The All Wales Medicines Strategy Group stated: *In the absence of a submission from the holder of the marketing authorisation, lidocaine/prilocaine (Tempe®) cannot be endorsed for use within NHS Wales for the treatment of primary premature ejaculation in adult men.*
FORMULARY STATUS	Non formulary
PBR STATUS	Inclusive of tariff
COMMISSIONING IMPLICATIONS	This treatment does not represent a cost-effective treatment option for the NHS.

RELEVANT CLINICAL DELIVERY GROUP	N/A
PATIENT PATHWAY IMPLICATIONS	The licensed oral treatment for premature ejaculation dapoxetine is not included on the Dorset formulary as the cost of dapoxetine is significantly greater than that of other SSRIs used off-label, the evidence for its use is limited and long-term safety outcomes are not available.
SUMMARY OF EVIDENCE TO SUPPORT FORMULARY STATUS	Clinical efficacy of lidocaine/prilocaine in males with PE was demonstrated in two multi-centre, multinational, randomised, double-blind, placebo controlled studies, both followed by an open-label phase. In the general population of patients with PE, lidocaine/prilocaine was shown to increase the time to achieve ejaculation after penetration (intra-vaginal ejaculatory latency time or IELT, an indicator of pharmacological activity); it also increased control over ejaculation and reduced the feelings of distress in patients with premature ejaculation as measured by the Index of Premature Ejaculation (IPE). During the 3 months of the double-blind treatment phase, the average IELT increased from 0.58 to 3.17 minutes in the Lidocaine/Prilocaine Plethora group and from 0.56 to 0.94 minutes in the placebo group. The clinically significant increases in IELT were paralleled by significant differences in the IPE scores ($p < 0.0001$).
ASSESSMENT OF COST IMPLICATIONS	Fortacin® is available on private prescription at an approximate cost of £100 from certain online pharmacies.
REFERENCES	http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Public_assessment_report/human/002693/WC500155496.pdf https://www.sps.nhs.uk/medicines/lidocaine-prilocaine/ http://www.awmsg.org/awmsgonline/app/sitesearch;jsessionid=83310c6e81dbad21fd59cc05ea8a?execution=e1s1 http://www.plethorasolutions.co.uk/fortacin-professional-facts.php
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REVIEW DATE	March 2019 or before, in light of new information.
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