



Final Appraisal Recommendation

Advice No: 0819 – May 2019

**Doxylamine succinate/pyridoxine hydrochloride (Xonvea®)
10 mg/10 mg gastro-resistant tablets**

Submission by Alliance Pharmaceuticals Ltd

Recommendation of AWMSG

Doxylamine succinate/pyridoxine hydrochloride (Xonvea®) is not recommended for use within NHS Wales for the treatment of nausea and vomiting of pregnancy (NVP) in women who do not respond to conservative management.

The cost-effectiveness data presented in the submission were insufficient for AWMSG to recommend its use.

Key factor(s) influencing the recommendation:

- There are uncertainties around the hospitalisation rate and dose used in the economic model provided in the company's submission. This together with the small utility gains, means there are limitations to the economic analyses.
- The lack of direct and indirect comparative data between doxylamine/pyridoxine and its comparators also limits the economic analyses as it assumes there is no difference between the comparators and placebo.

Additional note(s):

- Please refer to the Summary of Product Characteristics for the full licensed indication.
- Patients who are currently being treated with doxylamine succinate/pyridoxine hydrochloride (Xonvea®) for the indication stated above should have the option to continue their therapy until they and their clinicians consider it appropriate to stop.

In reaching the above recommendation AWMSG has taken account of the appraisal documentation prepared by the AWMSG Secretariat (reference number 2170), which includes the AWMSG Secretariat Assessment Report (ASAR), the Preliminary Appraisal Recommendation (PAR) and the applicant company's response to the PAR, clinical expert opinion (where available), the views of patients/patient carers (where available) and the lay member perspective.



This recommendation has been ratified by Welsh Government and will be considered for review every three years.

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