Grŵp Strategaeth Meddyginiaethau Cymru Gyfan
All Wales Medicines Strategy Group

Final Appraisal Recommendation

Advice No: 0919 – June 2019

Rufinamide (Inovelon®) 40 mg/ml oral suspension

Limited submission by Eisai Ltd

Recommendation of the All Wales Medicines Strategy Group

Rufinamide (Inovelon®) is recommended as an option for restricted use within NHS Wales.

Rufinamide (Inovelon®) is licensed as adjunctive therapy in the treatment of seizures associated with Lennox-Gastaut syndrome in patients 1 year of age and older.

Rufinamide (Inovelon®) is restricted for use where other adjunctive treatments have proved sub-optimal or have not been tolerated.

Rufinamide (Inovelon®) is not recommended for use within NHS Wales outside of this subpopulation.

Additional note(s):

- AWMSG considered that rufinamide (Inovelon®) satisfied the AWMSG criteria for orphan status.
- This advice incorporates and replaces the existing AWMSG recommendation for rufinamide (Inovelon®) as an option for use as adjunctive therapy in the treatment of seizures associated with Lennox-Gastaut syndrome in patients 4 years of age and older where other adjunctive treatments have proved sub optimal or have not been tolerated (advice number 3312, originally published October 2012).

In reaching the above recommendation AWMSG has taken account of the appraisal documentation prepared by the AWMSG Secretariat (reference number 991), 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.

The All Wales Therapeutics and Toxicology Centre (AWTTC) reviewed this appraisal recommendation in June 2022. No new evidence was identified that is likely to significantly affect the current recommendation. Therefore, this recommendation has been transferred to AWMSG's static list of medicine recommendations.