Grŵp Strategaeth Meddyginiaethau Cymru Gyfan
All Wales Medicines Strategy Group

Final Appraisal Recommendation

Advice No: 2617 – November 2017

Stiripentol (Diacomit®) 250 mg and 500 mg hard capsules; 250 mg and 500 mg powder for oral suspension in sachet

Resubmission by Biocodex

Recommendation of AWMSG

Stiripentol (Diacomit®) is recommended for use within NHS Wales for use in conjunction with clobazam and valproate as adjunctive therapy of refractory generalized tonic-clonic seizures in patients with severe myoclonic epilepsy in infancy (SMEI, Dravet syndrome) whose seizures are not adequately controlled with clobazam and valproate.

Additional note(s):

- AWMSG considered that stiripentol (Diacomit®) satisfied the AWMSG criteria for a medicine developed specifically for rare diseases as an ultra-orphan equivalent.

In reaching the above recommendation AWMSG has taken account of the appraisal documentation prepared by the AWMSG Secretariat (reference number 3468), 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.

Marketing authorisation holder on first issue	Biocodex
Date of first issue	November 2017
Last reviewed	November 2020

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NICE has accredited the process used by the All Wales Medicines Strategy Group (AWMSG) to produce its final appraisal recommendations. Accreditation is valid for 5 years from October 2016. More information on accreditation can be viewed at http://www.nice.org.uk/about/what-we-do/accreditation