Grŵp Strategaeth Meddyginiaethau Cymru Gyfan All Wales Medicines Strategy Group

Final Appraisal Recommendation Advice No: 1821 – December 2021

Dabigatran etexilate (Pradaxa[®]) 75 mg, 110 mg and 150 mg hard capsules

Licence extension for paediatric use submission by Boehringer Ingelheim Ltd.

Recommendation of AWMSG

Dabigatran etexilate (Pradaxa[®]) hard capsules are recommended as an option for use within NHS Wales, for the treatment of VTE and prevention of recurrent VTE in paediatric patients from 8 years to less than 18 years of age.

Additional note(s):

• See NICE guidance for dabigatran (Pradaxa[®]) for the treatment and secondary prevention of deep vein thrombosis and/or pulmonary embolism in adults (TA327, originally published December 2014).

In reaching the above recommendation AWMSG has taken account of the appraisal documentation prepared by the AWMSG Secretariat (reference number 2293), which includes the All Wales Therapeutics and Toxicology Centre (AWTTC) assessment, 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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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