

Clinical Study Synopsis for Public Disclosure

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1. ABSTRACT

Name of company: Boehringer Ingelheim			
Name of finished medicinal product: Pradaxa pellets.			
Name of active ingredient: dabigatran etexilate			
Report date: 04 November 2025	Study number: 1160-0309	Version/Revision: 1.0	Version/Revision date: 22 October 2025
Title of study:	Safety and effectiveness of Pradaxa oral pellet formulation for treatment of acute venous thromboembolic events (VTE) and/or for risk reduction of recurrence of VTE in pediatric patients aged 3 months to less than 12 years in a real-world setting: a prospective non-interventional study conducted in the United States		
Keywords:			
Rationale and background:	Pradaxa Pellets are a direct thrombin inhibitor that was approved on 21 Jun 2021 by the Food and Drug Administration (FDA) in the United States for the treatment of VTE and to reduce the risk of recurrence of VTE in pediatric patients aged 3 months to less than 12 years. The overall safety and efficacy of the pellets in pediatric patients was established in 2 clinical trials. However, the United States FDA requested further safety and effectiveness data in a real world setting in children aged 3 months to less than 12 years		
Research question and objectives:	To obtain further safety and effectiveness data on Pradaxa Pellets in children aged 3 months to less than 12 years in a routine clinical practice setting PRIMARY OBJECTIVE To estimate the cumulative incidence of clinically relevant bleeding events defined as the composite of Major bleeding events (MBE) and clinically relevant non-major (CRNM) bleeding events (according to recommendations from the Pediatric and Neonatal Thrombosis & Hemostasis Subcommittee of the Scientific and Standardization Committee of the International Society on Thrombosis and Haemostasis SECONDARY OBJECTIVES To estimate occurrence of recurrent VTE, mortality related to thrombotic or thromboembolic events, all bleeding events, post-thrombotic syndrome, adverse events and serious adverse events as well as thrombotic burden at the end of treatment and duration and compliance of treatment with dabigatran		

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Study design:	This was a non-interventional national multi-center study based on newly collected data of pediatric patients anticoagulated with Pradaxa Pellets for treatment of VTE and/or for risk reduction of recurrence of VTE in the context of routine anticoagulation care provided in the United States in children aged 3 months to less than 12 years. Three types of patients were considered for inclusion into the study: 1) Patients who needed treatment of VTE and who have been treated with a parenteral anticoagulant for at least 5 days (hereinafter referred to “VTE treatment”) 2) Patients who needed treatment to reduce the risk of recurrence of VTE and who have been previously treated (hereinafter referred to “risk reduction of recurrence of VTE”) 3) Patients who were taking Pradaxa Pellets for VTE treatment or to reduce the risk of VTE recurrence and in a manner not aligned with prescribing information (off-label use)		
Setting:	Participants were enrolled at three sites through the United States Children's Healthcare Advancement in Thrombosis (CHAT) consortium between 31 October 2023 and 28 April 2025		
Subjects and study size, including dropouts:	Out of the six patients screened, five patients aged 3 months to less than 12 years were enrolled into the study		
Variables and data sources:	Primary exposure: Information on Pradaxa Pellets (indication for therapy, dose prescribed, and dates of treatment) was ascertained via medication status questions during study visits, Primary outcome: Incidence of clinically-relevant bleeding events Secondary outcomes: Incidence of recurrent VTE, any bleeding events, and adverse events Other variables included demographics (e.g. age, weight, BMI, gender, race, ethnicity), procedures related to VTE diagnostic modalities, medical history, VTE characteristics and occurrence of AEs / SAEs. Data were collected at study visits via both patient/caregiver questioning and medical records		

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Results:	The study was terminated early due to low prescribing in the US and low study enrollment (5 out of 300 planned patients recruited), so no meaningful data analysis or interim analysis was possible. Results are presented in descriptive only. Mean (SD) combined age in years was 7.73 (3.13), with two male and three female participants. Race breakdown included two Black/AA participants, two White and one who refused to identify. For ethnicity, two reported as Hispanic or Latino, two reported as non-Hispanic or Latino and one declined to answer. Four participants completed data collection, and one did not complete due to early study termination. Primary/Secondary outcome At the time of study termination, one participant, out of five enrolled, had developed a clinically relevant non-major bleeding event, which resolved. The event occurred five days after the participant was off Pradaxa Pellets and on a different anticoagulant. Two participants developed new VTE or recurrent VTE events identified at least 7 days after diagnosis of the index VTE. One patient had two events in the same vascular location as the index VTE at two different interim follow up times. The other patient developed one VTE in the same vascular location as the index VTE at 6 months follow up time. All VTE events were complete occlusion and Pradaxa Pellets was not stopped after the diagnosis of the recurrent VTE. No mortality related to thrombotic events occurred. No PTS or thrombotic burden at the end of treatment period was reported. AE/SAE overall summary Four patients had AEs with zero reporting severe AEs. One patient had AE (Atrial thrombosis, Cardiac ventricular thrombosis) leading to discontinuation of trial drug. Two patients had serious AEs (Rhinitis allergic, chest pain, Atrial thrombosis, Cardiac ventricular thrombosis, Tricuspid valve incompetence, Pyrexia) which required or prolonged hospitalization. No patients reported serious AEs resulting in death, life threatening, persistent or significant disability/incapacity, congenital anomaly or birth defects.		
Discussion:	The number of prescriptions written for Pradaxa Pellets during the course of the study was extremely low. As this was a non-interventional study, the very low number of patients prescribed Pradaxa Pellets made enrollment of		

