

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**215859Orig1s000**

**CLINICAL REVIEW(S)**

Clinical/CDTL/DD Review  
 Ann T. Farrell, MD  
 NDA 215859  
 XARELTO/rivaroxaban

CLINICAL REVIEW

Application Type	505b2 NDA for a new formulation and two indications
Application Number(s)	NDA 215859
Priority or Standard	Priority review containing a response to a Written Request
Submit Date(s)	06/22/21
Received Date(s)	06/22/21
PDUFA Goal Date	12/22/2021
Division/Office	DNH/OCHEN
Reviewer Name(s)	Carrie Diamond, MD Ann T. Farrell, MD (this also serves as the DD and CDTL review)
Review Completion Date	12/20/2021
Established/Proper Name (Proposed) Trade Name	XARELTO rivaroxaban
Applicant	Janssen
Dosage Form(s)	Currently marketed – tablets; proposed formulation – oral solution
Applicant Proposed Dosing Regimen(s)	Age and weight-based algorithm ranging from 1 to 3 times a day
Applicant Proposed Indication(s)/Population(s)	<p>1) Treatment of Venous Thromboembolism and Reduction in Risk of Recurrent Venous Thromboembolism in Pediatric Patients          XARELTO is indicated for the treatment of venous thromboembolism (VTE) and the reduction in the risk of recurrent VTE in pediatric patients from birth to less than 18 years after at least 5 days of initial parenteral anticoagulant treatment.</p> <p>2) Thromboprophylaxis in Pediatric Patients with Congenital Heart Disease after the Fontan Procedure          XARELTO is indicated for thromboprophylaxis in pediatric patients aged 2 years and older with congenital heart disease who have undergone the Fontan procedure.</p>
Recommendation on Regulatory Action	Approval
Recommended Indication(s)/Population(s) (if applicable)	<p>1) Treatment of Venous Thromboembolism and Reduction in Risk of Recurrent Venous Thromboembolism in Pediatric Patients          XARELTO is indicated for the treatment of venous thromboembolism (VTE) and the reduction in the risk of</p>

	<p>recurrent VTE in pediatric patients from birth to less than 18 years after at least 5 days of initial parenteral anticoagulant treatment.</p> <p>2) Thromboprophylaxis in Pediatric Patients with Congenital Heart Disease after the Fontan Procedure</p> <p>XARELTO is indicated for thromboprophylaxis in pediatric patients aged 2 years and older with congenital heart disease who have undergone the Fontan procedure.</p>
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