Xarelto® (rivaroxaban) 2.5 mg – First-time generic

- On March 7, 2025, Lupin launched an AB-rated generic version of Janssen's Xarelto (rivaroxaban) 2.5 mg tablets.
    - Taro also received FDA approval of an AB-rated generic version of Xarelto 2.5 mg tablets on March 3, 2025; launch is pending.
    - Xarelto is also available as 10 mg, 15 mg, and 20 mg tablets and an oral suspension.
- Generic Xarelto and brand Xarelto are approved for the following indications:
    - In combination with aspirin, to reduce the risk of major cardiovascular events (cardiovascular death, myocardial infarction, and stroke) in adult patients with coronary artery disease
    - In combination with aspirin, to reduce the risk of major thrombotic vascular events (myocardial infarction, ischemic stroke, acute limb ischemia, and major amputation of a vascular etiology) in adult patients with peripheral artery disease (PAD), including patients who have recently undergone a lower extremity revascularization procedure due to symptomatic PAD.
- Higher dosages of brand Xarelto are also approved for the following indications:
    - Reduction of risk of stroke and systemic embolism in nonvalvular atrial fibrillation
    - Treatment of deep vein thrombosis (DVT)
    - Treatment of pulmonary embolism (PE)
    - Reduction in the risk of recurrence of DVT and/or PE
    - Prophylaxis of DVT following hip or knee replacement surgery
    - Prophylaxis of venous thromboembolism in acutely ill medical patients at risk for thromboembolic complications not at high risk of bleeding
    - Treatment of venous thromboembolism and reduction in risk of recurrent venous thromboembolism in pediatric patients
    - Thromboprophylaxis in pediatric patients with congenital heart disease after the Fontan procedure.
- Xarelto carries a boxed warning for premature discontinuation of Xarelto increases the risk of thrombotic events, and spinal/epidural hematoma.
- According to IQVIA®, Xarelto 2.5 mg tablets had annual U.S. sales of $446 million as of January 2025.

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