Xarelto® (rivaroxaban) 2.5, 10, 15 and 20 mg film-coated tablets  
Prescribing Information (Refer to full Summary of Product Characteristics (SmPC) before prescribing) 

Presentation: 2.5 mg/10 mg/15 mg/20 mg rivaroxaban tablet.  
Indication(s): 2.5 mg, co-administered with acetylsalicylic acid (ASA) alone or with ASA plus clopidogrel or ticlopidine, is indicated for the prevention of atherothrombotic events in adult patients after an acute coronary syndrome (ACS) with elevated troponin (biomarker of myocardial injury), co-administered with acetylsalicylic acid (ASA), is indicated for the prevention of atherothrombotic events in adult patients with coronary artery disease (CAD) or symptomatic peripheral artery disease (PAD) at high risk of ischaemic events. 10 mg Prevention of venous thromboembolism (VTE) in adult patients undergoing elective hip or knee replacement surgery. Treatment of deep vein thrombosis (DVT) & pulmonary embolism (PE), & prevention of recurrent DVT & PE in adults. (see W&P for haemodynamically unstable PE patients).  
15 mg/20 mg Prevention of stroke & systemic embolism in adult patients with non-valvular atrial fibrillation with one or more risk factors such as congestive heart failure, hypertension, age ≥ 75, diabetes mellitus, prior stroke or transient ischaemic attack (SAF). Treatment of DVT & PE (see W&P for haemodynamically unstable PE patients).  
Posology & method of administration: 2.5 mg – Oral b.i.d. dose; patients should also take a daily dose of 75 – 100 mg ASA or a daily dose of 75 – 100 mg ASA in addition to either a daily dose of 75 mg clopidogrel or a standard daily dose of ticlopidine. Start Xarelto as soon as possible after stabilisation, including reversal of any underlying conditions – the earlier the initiation of treatment the better.  
10 mg – hip or knee replacement surgery: Oral o.d. dose; initial dose taken 6 to 10 hours after surgery provided haemostasis established. DVT & PE: When extended prevention of recurrent DVT and PE is indicated (following completion of at least 6 months therapy for DVT or PE), the recommended dose is 10 mg o.d. in patients in whom the risk of recurrent DVT or PE is considered high, such as those with complicated comorbidities, or who have developed recurrent DVT or PE on extended prevention with Xarelto 10 mg o.d., a dose of Xarelto 20 mg o.d. should be considered.  
15 mg/20 mg – Take with food; SPAF: 20 mg orally o.d. DVT & PE: 15 mg b.i.d. for 3 weeks followed by 20 mg o.d. for continued treatment & prevention of recurrent DVT & PE.  
All strengths: Refer to SmPC for full information on duration of therapy & conversion to from Vitamin K antagonists (VKA) or parenteral anticoagulants.  
Special populations: Patients undergoing cardioversion: Xarelto can be initiated or continued in patients who may require cardioversion. Patients with non-valvular atrial fibrillation who undergo PCI (percutaneous coronary intervention) with stent placement. There is limited experience of a reduced dose of 15 mg Xarelto once daily (or 10 mg Xarelto once daily for patients with moderate renal impairment [creatinine clearance 30 – 49 ml/min]) in addition to a P2Y12 inhibitor for a maximum of 12 months in patients with non-valvular atrial fibrillation who require oral anticoagulation & undergo PCI with stent placement.  
Renal impairment: mild: (creatinine clearance 50–80 ml/min) - no dose adjustment. 2.5 mg/10 mg - moderate (creatinine clearance 30–49 ml/min) - the usual oral dose administered (i.e. 2.5 mg/10 mg). (creatinine clearance 30–49 ml/min) - severe (creatinine clearance 15–29 ml/min) - SPAF: reduce dose to 15 mg o.d., DVT & PE: 15 mg b.i.d. for 3 weeks, thereafter 20 mg o.d. Consider reduction from 20 mg to 15 mg o.d. if patient's bleeding risk outweighs risk for recurrent DVT & PE.  
All strengths – Severe impairment: limited data indicate rivaroxaban concentrations are significantly lower in patients with Child Pugh B & C Paediatrics: Not recommended. Contra-indications:  
Hypersensitivity to active substance or any excipient; active clinically significant bleeding, lesion or condition considered to confer a significant risk for major bleeding (refer to SmPC); concomitant treatment with any other anticoagulant drug, including an antiplatelet agent, angiotensin converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) and any other oral antiplatelet agent, and/or aspirin or clopidogrel or ticlopidine or ticagrelor, or any other antiplatelet agent, or aspirin or clopidogrel or ticlopidine; or clopidogrel/ticlopidine; or a non-steroidal anti-inflammatory drug (NSAID) or any other antiplatelet drug is contraindicated.  
Concomitant use of rivaroxaban should be avoided if there is a risk of intracranial bleeding. Xarelto is contraindicated in patients with active or suspected meningitis or encephalitis.  
Warnings & precautions (W&P): Clinical surveillance in line with anticoagulant practice is recommended throughout the treatment period. Discontinue if severe haemorrhage occurs. Increasing age may increase haemorrhagic risk. Xarelto should be used with caution at the first occurrence of a serious adverse event, or any other sign of hypersensitivity in conjunction with mucosal lesions.  
Not recommended: in patients with an increased bleeding risk (refer to SmPC); in patients receiving concomitant systemic treatment with strong concurrent CYP3A4- & P-gp-inhibitors, i.e. azole-antimycotics or HIV protease inhibitors; in patients with prosthetic heart valves; for patients with a history of thrombosis diagnosed with antiphospholipid syndrome; Xarelto should not be used for thromboprophylaxis in patients having undergone transcatheter aortic valve replacement (TAVR).  
2.5 mg treatment in combination with antiplatelet agents other than ASA & clopidogrel/ticlopidine; 10 mg/15 mg/20 mg in haemodynamically unstable PE patients or patients who require thrombolyis or pulmonary embolus. Use with caution: in patients treated concomitantly with medicines affecting haemostasis; when neurexial anaesthesia or spinal/epidural puncture is employed; in patients at risk of ulcerative gastrointestinal disease (prophylactic treatment may be considered); 2.5 mg in patients ≥ 75 years of age or with lower body weight (<60kg); in CAD patients with severe symptomatic heart failure. Patients on treatment with Xarelto & ASA or Xarelto & ASA plus clopidogrel/ticlopidine should only receive concomitant treatment with NSAI’s if the benefit outweighs the bleeding risk.  
2.5 mg/10 mg in patients with moderate renal impairment concomitantly receiving other medicinal products which increase rivaroxaban plasma concentrations. 15 mg/20 mg in patients with renal impairment concomitantly receiving other medicinal products which increase rivaroxaban plasma concentrations.  
All strengths: There is no need for monitoring of coagulation parameters during treatment with rivaroxaban in clinical routine, if clinically indicated rivaroxaban levels can be measured by calibrated quantitative anti-Factor Xa tests. Xarelto contains lactose.  
Interactions: Concomitant use with strong inhibitors of both CYP3A4 & P-gp not recommended as clinically relevant increased rivaroxaban plasma concentrations are co-administered.  
Use with caution in patients concomitantly receiving NSAI’s, ASA or platelet aggregation inhibitors due to the increased bleeding risk; use with caution in patients concomitantly receiving SSRIs/SNRIs due to a possible increased bleeding risk. Concomitant use of strong CYP3A4 inducers should be avoided unless patient is closely observed for signs & symptoms of thrombosis.  
Pregnancy & breast feeding: Contra-indicated.  
Effects on ability to drive & use machines: syncope (uncommon) & dizziness (common) were reported. Patients experiencing these effects should not drive or use machines.  
Undesirable effects: Common: anaemia, dizziness, headache, eye haemorrhage, hypotension, haematoma, epistaxis, haemoptysis, gingival bleeding, GI tract haemorrhage, GI & abdominal pains, dyspepsia, nausea, constipation, diarrhoea, vomiting, increase in transaminases as AST, rash, ecchymosis, cutaneous & subcutaneous haemorrhage, pain in extremity, urgenital tract haemorrhage (menorrhagia very common in women <55 yrs treated for DVT, PE & prevention of recurrence), renal impairment, fever, peripheral oedema, decreased general strength & energy, post-procedural haemorrhage, conjuction, wound secretion.  
Serious: cf. CI/Warnings & Precautions in addition: thrombocytosis, thrombocytopenia, Stevens-Johnson syndrome/Toxic Epidermal Necrolysis, DRESS syndrome, anaphylactic reactions including shock, angioedema & allergic oedema, occult bleeding/haemorrhage from any tissue (e.g. cerebral & intracranial, haemarthrosis, muscle) which may lead to complications (incl. compartment syndrome, renal failure, fatal outcome), syncope, tachycardia, hepatic impairment, cholesterol & hepatitis (incl. hepatocellular, increases in bilirubin, blood alkaline phosphatase & GGT, increased conjugated bilirubin, jaundice, vascular pseudoaneurysm following percutaneous vascular intervention. Prescribers should consult SmPC in relation to full side effect information. Overdose: A specific reversal agent is available, refer to the SmPC for andexanet alfa.  
Legal Category: POM Package Quantity & Basic NHS Costs: 2.5 mg = 56 tablets: £50.40. 10 mg = 10 tablets: £8.00. 30 tablets: £54.00 & 100 tablets: £180.00. 15 mg = 14 tablets: £25.20. 28 tablets: £50.40, 42 tablets: £75.60. 100 tablets: £180.00. 20 mg = 28 tablets: £50.40, 100 tablets: £180.00. 20 mg Treatment Initiation pack (42 tablets of 15mg, 7 tablets of 20mg): £88.20 MA Number(s): 2.5 mg - EU/10/0472/025-035, 041, 046-047. 10 mg - EU/10/0472/021-010, 022, 042-045 15mg/20 mg - EU/10/0472/011-21, 023-024, 036-040, 043-047. 20 mg - EU/10/0472/011-21, 023-024, 036-040, 043-047. Further information available from Bayer plc. 400 South Oak Way, Reading, RG2 6AD, U.K. Telephone: 0118 206 3000. Date of preparation: November 2019.  
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