



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: 2.5mg/10mg/15mg/20mg rivaroxaban tablet. **Indication(s):** **2.5mg** Xarelto, 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 cardiac biomarkers. Xarelto, 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. **10mg** 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). **15mg/20mg** 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 (SPAF). Treatment of DVT & PE, & prevention of recurrent DVT & PE in adults (see W&P for haemodynamically unstable PE patients). **Posology & method of administration:** **2.5mg** – 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 revascularisation for ACS; at the earliest 24 hours after admission & at discontinuation of parenteral anticoagulation. If dose is missed take next dose, do not double the dose. **10mg** – *hip or knee replacement surgery:* Oral *a.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 *a.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 *a.d.*, a dose of Xarelto 20 mg *a.d.* should be considered. **15mg/20mg** – Take with food. **SPAF:** 20 mg orally *a.d.* **DVT & PE:** 15 mg *b.i.d.* for 3 weeks followed by 20 mg *a.d.* for continued treatment & prevention of recurrent DVT & PE. **All strengths** – Refer to SmPC for full information on duration of therapy & converting 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; **2.5mg/10mg** – moderate (creatinine clearance 30-49 ml/min) – no dose adjustment. **15mg/20mg** – moderate (creatinine clearance 30-49 ml/min) & severe (creatinine clearance 15-29ml/min) – **SPAF:** reduce dose to 15mg *a.d.*, **DVT & PE:** 15 mg *b.i.d.* for 3 weeks, thereafter 20mg *a.d.* Consider reduction from 20mg to 15mg *a.d.* if patient's bleeding risk outweighs risk for recurrent DVT & PE; **All strengths** – Severe impairment: limited data indicate rivaroxaban concentrations are significantly increased, use with caution. Creatinine clearance <15 ml/min – not recommended. **Hepatic impairment:** Do not use in patients with coagulopathy & clinically relevant bleeding risk including cirrhotic 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 anticoagulants except under specific circumstances of switching anticoagulant therapy or when unfractionated heparin is given at doses necessary to maintain an open central venous or arterial catheter; hepatic disease associated with coagulopathy & clinically relevant bleeding risk including cirrhotic patients with Child Pugh B & C; pregnancy & breast feeding. **2.5mg** – concomitant treatment of ACS with antiplatelet therapy in patients with a prior stroke or transient ischaemic attack; concomitant treatment of CAD/PAD with ASA in patients with previous haemorrhagic or lacunar stroke, or any stroke within a month. **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 discontinued at the first appearance of a severe skin rash, 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 recently undergone transcatheter aortic valve replacement (TAVR); **2.5mg** treatment in combination with antiplatelet agents other than ASA & clopidogrel/ticlopidine; **10mg/15mg/20mg** in haemodynamically unstable PE patients or patients who require thrombolysis or pulmonary embolectomy. **Use with caution:** in patients treated concomitantly with medicines affecting haemostasis; when neuraxial anaesthesia or spinal/epidural puncture is employed; in patients at risk of ulcerative gastrointestinal disease (prophylactic treatment may be considered); **2.5mg** in patients ≥ 75 years of age or with lower body weight (<60 kg); 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 NSAIDs if the benefit outweighs the bleeding risk. **2.5mg/10mg** in patients with moderate renal impairment concomitantly receiving other medicinal products which increase rivaroxaban plasma concentrations; **15mg/20mg** 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 observed. Avoid co-administration with dronedarone. 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, pruritus, rash, ecchymosis, cutaneous & subcutaneous haemorrhage, pain in extremity, urogenital 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, contusion, 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, cholestasis & hepatitis (incl. hepatocellular injury), 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:** No specific antidote is available. **Legal Category:** POM. **Package Quantities & Basic NHS Costs:** **2.5mg** – 56 tablets: £50.40. **10mg** – 10 tablets: £18.00, 30 tablets: £54.00 & 100 tablets: £180.00. **15mg** – 14 tablets: £25.20, 28 tablets: £50.40, 42 tablets: £75.60, 100 tablets: £180.00; **20mg** – 28 tablets: £50.40, 100 tablets: £180.00; Treatment Initiation pack (42 tablets of 15mg, 7 tablets of 20mg): £88.20 **MA Number(s):** **2.5mg** – EU/1/08/472/025-035, 041, 046-047. **10mg** – EU/1/08/472/001-10, 022, 042-045 **15mg/20mg** – EU/1/08/472/011-21, 023-024, 036-040, 048-049 **Further information available from:** Bayer plc, 400 South Oak Way, Reading, RG2 6AD, U.K. Telephone: 0118 206 3000. **Date of preparation:** September 2019

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Adverse events should be reported. Reporting forms and information can be found at <https://yellowcard.mhra.gov.uk> or search for MHRA Yellow Card in Google Play or Apple App Store. Adverse events should also be reported to Bayer plc. Tel.: 0118 206 3500, Fax.: 0118 206 3703, Email: pvuk@bayer.com



An update of VTE management, treatment and pathway in Somerset

Tuesday 3rd December 2019, 13:30 – 16:45

Yeovil Court Hotel, West Coker Rd, Yeovil BA20 2HE

Please note: This meeting will include promotional content

The X-IMPACT training programme is fully organised and funded by Bayer.



Prescribing information can be found on the back page.

Date of preparation: September 2019
RP-XAR-GB-1205



Dear Health Care Professional,

Direct oral anticoagulants (DOACs) are recommended as an option for the prevention of stroke associated with non-valvular Atrial Fibrillation (AF) and for the treatment and secondary prevention of venous thromboembolism (VTE). The evolution of clinical practice in these areas has resulted in significant change in clinical practice, guidelines and treatment options.

Bayer are delighted to offer the X-IMPACT programme – a variety of expert led educational meetings dedicated to improving anticoagulation management, aiming to support optimal delivery of care and, as such, best practices.

This meeting has been specifically designed to focus on improving anticoagulation practices for the treatment of PE and DVT/prevention. The following topics will be discussed at the meeting:

- The VTE outlook: Current and future management of VTE.
- Cancer-associated thrombosis: The scale of the problem and approaches to management.
- The local treatment pathway for VTE patients.

Invitations are open to members of the medical profession only, and delegate spaces will be allocated on a first-come, first-served basis.

Lunch and refreshments will be offered in accordance with the ABPI Code of Practice.

We hope you will be able to join us and look forward to hearing from you soon!

Best wishes,

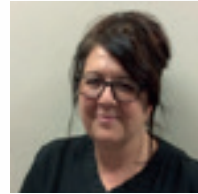
Sophie Pribojac

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X-IMPACT is an educational platform led by Bayer offering free training to a breadth of healthcare professionals. The X-IMPACT training programme is fully organised and funded by Bayer.

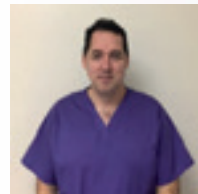
Agenda

Speakers



Julie Reeve

*Nurse Consultant Emergency Medicine,
Yeovil District Hospital, Yeovil*



Les Reed

*Lead Nurse Practitioner,
Ambulatory Emergency Care,
Yeovil District Hospital, Yeovil*

TIME	SESSION
13:30 – 14:00	Registration and Lunch
14:00 – 14:30	How to wells score and D-Dimer
14:30 – 15:00	Local Pathway for VTE and the hospital service. When to refer and who follows up.
15:00 – 15:15	Tea and Coffee
15:15 – 16:00	Management and treatment of VTE, long term DVT treatment and cancer associated thrombosis.
16:00 – 16:45	Case studies on complicated cases.

Register your attendance via:

Sophie Pribojac

Email: Sophie.pribojac.ext@bayer.com Phone: 07970 890464

PRIVACY NOTICE: Bayer plc is the data controller of any personal data that you provide for the purposes of registration for the meeting (e.g. name, organisation, title, contact details). The personal data that you provide will be used for the purpose of organising and administering the meeting, including by sending electronic reminders, for the purposes of customer relationship management and record keeping in accordance with Bayer's compliance requirements. For more information on how Bayer holds your personal data <https://www.bayer.co.uk/en/bayer-meetings-privacy-statement>