# ABBREVIATED PRESCRIBING INFORMATION

**Xarelto®, Rivaroxaban 15/ 20 mg film-coated tablets.** Approved name(s) of the active ingredient(s): Each film-coated tablet contains 15 mg and 20mg Rivaroxaban micronized. Excipients: Microcrystalline cellulose, croscarmellose sodium, lactose monohydrate, hypromellose, sodium laurilsulfate, magnesium stearate, macrogol 3350, titanium dioxide (E171), iron oxide red (E172). **Indication:** 1. Xarelto is indicated for prevention of stroke and systemic embolism in patients with nonvalvular atrial fibrillation. 2. Xarelto is indicated for the treatment of Deep Vein Thrombosis (DVT) and for the prevention of recurrent DVT and Pulmonary Embolism (PE). **Dosage and method of administration: 1. SPAF** The recommended dose is 20 mg once daily. For patients with moderate renal impairment (creatinine clearance (CrCl):<50-30 mL/min) the recommended dose is 15 mg once daily taken with food. Patients with non-valvular atrial fibrillation who undergo PCI with stent placement should receive reduced dose of 15 mg Xarelto once daily (or 10 mg Xarelto once daily for patients with moderate renal impairment [CrCl: <50-30 mL/min]) in addition to a P2Y12 inhibitor. **2. DVT Treatment** The recommended dose for the initial treatment of acute DVT is 15 mg Xarelto twice daily for the first three weeks followed by 20 mg Xarelto once daily for the continued treatment and the prevention of recurrent DVT and PE. Following completion of at least 6 months treatment for DVT, Xarelto 10 mg once daily or Xarelto 20 mg once daily is recommended based on an individual assessment of the risk of recurrent DVT or PE against the risk for bleeding. Xarelto 15 mg tablets and Xarelto 20 mg tablets should be taken with food. **Contraindications:** Xarelto is contraindicated in patients with hypersensitivity to Rivaroxaban or any excipient of the tablet, inpatients with clinically significant active bleeding (e.g., intracranial bleeding, gastrointestinal bleeding), in patients with hepatic disease which is associated with coagulopathy leading to a clinically relevant bleeding risk, Pregnancy and Breast Feeding. **Warnings & Precautions SPAF:** Xarelto is not recommended for thromboprophylaxis in patients having recently undergone transcatheter aortic valve replacement (TAVR), in patients with prosthetic heart valves, in children less than 18 years, in patients receiving concomitant systemic treatment with azole-antimycotics (e.g. ketoconazole) or HIV protease inhibitors (e.g. ritonavir), in patients with severe renal impairment (CrCl<15 ml/min), in patients with a history of thrombosis who are diagnosed with antiphospholipid syndrome and are persistently triple positive (for lupus anticoagulant, anticardiolipin antibodies, and anti–beta 2-glycoprotein I antibodies) . 2. DVT Treatment Xarelto is to be used with caution in patients with moderate renal impairment receiving co-medications leading to increased Rivaroxaban plasma concentrations, use of Xarelto is not recommended in patients with severe renal impairment. Xarelto like other antithrombotics should be used with caution in patients with an increased bleeding risk. Xarelto should be used in women of childbearing potential only with effective contraception. Safety and efficacy have not been established in children and adolescents below 18 years. If an invasive procedure or surgical intervention is required, Xarelto should be stopped at least 24 hours before the intervention, if possible and based on clinical judgment of the physician. When neuraxial (epidural/spinal) anesthesia or spinal puncture is performed, patients treated with antithrombotics for prevention of thromboembolic complications are at risk for development of an epidural or spinal hematoma which may result in long-term paralysis. The physician should consider the potential benefit versus the risk before neuraxial intervention in patients anticoagulated or to be anticoagulated for thromboprophylaxis. There is no clinical experience with the use of 15 mg and 20 mg rivaroxaban in these situations. For the removal of an epidural catheter and based on the general PK characteristics at least 2x half-life should elapse, i.e. at least 18 hour in young patients and 26 hours in elderly patients, after the last administration of Xarelto. Xarelto should be administered at earliest 6 hours after the removal of the catheter. If traumatic puncture occurs, the administration of Xarelto should be delayed for 24 hours. **Undesirable effects:** Common: Anemia, Eye hemorrhage, Gingival bleeding, Gastrointestinal tract hemorrhage (incl. rectal hemorrhage) Gastrointestinal and abdominal pains, Dyspepsia, Nausea, Constipation, Diarrhea, Fever, Edema peripheral, decreased general strength and energy, Vomiting, Postprocedural hemorrhage (incl. postoperative anemia and wound hemorrhage) Contusion, increase in transaminases, Pain in extremity, Dizziness, Headache, Syncope, Urogenital tract hemorrhage, Renal impairment (incl. blood creatinine increased, blood urea increased) Epistaxis, Hemoptysis, Pruritus (incl. uncommon cases of generalized pruritus) Rash, Ecchymosis, Cutaneous and subcutaneous hemorrhage, Hypotension, Hematoma. For full listing of undesirable effects, please refer to the full product insert. **For further prescribing information,** please contact: Bayer Zydus Pharma Private Limited, Bayer House, Central Avenue, Hiranandani Estate, Thane, Maharashtra, India Pin-400607. Email: medicalinfo.india@bayerzyduspharma.com. **Source:** Version No. XA_2022_02 dated 21 Oct 2022 Based on CCDS version 14 dated 13 Jul 2022 and CCDS version 15 dated 02 Aug 2022 and Patient counselling information from CCPI version 12 dated 01 Dec 2020 Rev: Oct 2022

# ABBREVIATED PRESCRIBING INFORMATION

**Xarelto® Rivaroxaban 2.5 mg film-coated tablets**. Approved name(s) of the active ingredient(s) Each film-coated tablet contains 2.5 mg Rivaroxaban. Indication 1. Rivaroxaban 2.5mg tablet, co-administered with Acetylsalicyclic 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.2. Rivaroxaban 2.5 mg tablet, 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. Dosage and method of administration: ACS After an ACS, the recommended vascular protection regimen is one tablet of 2.5 mg Xarelto twice daily. Patients should also take a daily dose of 75-100 mg ASA or a daily dose 75-100 mg ASA in addition to a daily dose of 75 mg clopidogrel or a standard daily dose of ticlopidine. Treatment with Xarelto 2.5 mg should be started as soon as possible after stabilization of the index ACS event (including revascularization procedures). Xarelto should be started earliest 24 hours after admission to hospital. Xarelto 2.5 mg should be started at the time when parenteral anticoagulation therapy would normally be discontinued. Treatment is recommended for at least 24 months. Patients after ACS continue to be at risk for cardiovascular events and therefore may benefit from extended treatment. CAD or PAD: The recommended vascular protection regimen for patients with CAD or PAD is one tablet of 2.5 mg Xarelto twice daily in combination with a daily dose of 75-100 mg ASA. Therapy with Xarelto should be continued long term provided the benefit outweighs the risk. In patients diagnosed with CAD or PAD, treatment with Xarelto 2.5 mg twice daily in combination with ASA 75-100 mg once daily can be started at any time. One 2.5 mg tablet of Xarelto should be taken twice daily. Xarelto 2.5 mg tablets may be taken with or without food. Contraindications Xarelto 2.5mg is contraindicated in patients with hypersensitivity to Rivaroxaban or any excipient of the tablet, in patients with clinically significant active bleeding (e.g., intracranial bleeding, gastrointestinal bleeding), in patients with hepatic disease which is associated with coagulopathy leading to a clinically relevant bleeding risk, Pregnancy and Breast Feeding, Warnings & Precautions: Xarelto is not recommended for thromboprophylaxis in patients having recently undergone transcatheter aortic valve replacement (TAVR), in patients with other prosthetic heart valves or other valve procedures, in patients receiving concomitant systemic treatment with azole-antimycotics (e.g. ketoconazole) or HIV protease inhibitors (e.g. ritonavir). in patients with severe renal impairment (CrC: <15 mL/min). Xarelto 2.5 mg bid should be avoided for the treatment of ACS in patients with a prior stroke or TIA, CAD or PAD patients with previous haemorrhagic or lacunar stroke and who have experienced an ischemic, non-lacunar stroke within the previous month have not been studied. Xarelto 2.5mg like other antithrombotics should be used with caution in patients with an increased bleeding risk such as congenital or acquired bleeding disorders, uncontrolled severe arterial hypertension, active ulcerative

gastrointestinal disease, recent gastrointestinal ulcerations, vascular retinopathy, recent intracranial or intracerebral hemorrhage, intraspinal or intracerebral vascular abnormalities, recent brain, spinal or ophthalmological surgery, bronchiectasis or history of pulmonary bleeding. Treatment in combination with other antiplatelet agents, e.g. prasugrel or ticagrelor, has not been studied and therefore, is not recommended. Xarelto should be used in women of childbearing potential only with effective contraception. Safety and efficacy have not been established in children and adolescents below 18 years. Xarelto is not recommended for patients with a history of thrombosis who are diagnosed with antiphospholipid syndrome and are persistently triple positive. Undesirable effects Common: Anemia, Eye hemorrhage, Gingival bleeding, Gastrointestinal tract hemorrhage (incl. rectal hemorrhage) Gastrointestinal and abdominal pains Dyspepsia Nausea Constipation & Diarrhea, Fever, Edema peripheral, decreased general strength and energy, Vomiting, Postprocedural hemorrhage (incl. postoperative anemia and wound hemorrhage) Contusion, Increase in transaminases Pain in extremity Dizziness Headache Syncope, Urogenital tract hemorrhage Renal impairment (incl. blood creatinine increased, blood urea increased, Epistaxis, Hemoptysis Pruritus(incl. uncommon cases of generalized pruritus) Rash Ecchymosis Cutaneous and subcutaneous hemorrhage, Hypotension, Haematoma. For full listing of undesirable effects, please refer to the full product insert. For further prescribing information, please contact Bayer Zydus Pharma Private Limited, Bayer House, Central Avenue, Hiranandani Estate, Thane, Maharashtra, India Pin-400607. Email: medicalinfo.india@bayerzuspharma.com. Source: Version No. XA_2022_02 dated 21 Oct 2022 Based on CCDS version 17 dated 13 Jul 2022 and Patient counselling information from CCPI version 15 dated 01 Dec 2020 Rev date: Oct 2022

## ABBREVIATED PRESCRIBING INFORMATION

**Xarelto®.Rivaroxaban 10 mg film-coated tablets**. Approved name(s) of the active ingredient(s): Each film-coated tablet contains 10 mg Rivaroxaban Excipients: Microcrystalline cellulose, croscarmellose sodium, lactose monohydrate, hypromellose, sodium laurilsulfate, magnesium stearate, macrogol 3350, titanium dioxide (E171), iron oxide red (E172 Indication: Xarelto is indicated for the prevention of venous thromboembolism (VTE) in adult patients undergoing elective hip or knee replacement surgery. Dosage and method of administration: The recommended dose for VTE prevention in major orthopedic surgery is one 10 mg tablet once daily. Xarelto 10 mg tablets may be taken with or without food. The initial dose should be taken within 6-10 hours after surgery provided that hemostasis has been established. After major hip surgery patients should be treated for 5 weeks. After major knee surgery patients should be treated for 2weeks. Contraindications: Xarelto is not recommended for thromboprophylaxis in patients having recently undergone transcatheter aortic valve replacement (TAVR) based on data from a randomized controlled clinical study comparing a Xarelto-regimen to an antiplatelet regimen Xarelto is contraindicated in patients with hypersensitivity to Rivaroxaban or any excipient of the tablet, in patients with clinically significant active bleeding (e.g., intracranial bleeding, gastrointestinal bleeding), in patients with hepatic disease which is associated with coagulopathy leading to a clinically relevant bleeding risk, Pregnancy and Breast Feeding. Warnings & Precautions: Xarelto is not recommended in patients receiving concomitant systemic treatment with azole-antimycotics (e.g. ketoconazole) or HIV protease inhibitors (e.g. ritonavir). These drugs are strong inhibitors of both CYP 3A4and P-gp. in patients with severe renal impairment (CrCl <15 ml/min), Xarelto has not been studied in interventional clinical trials in patients undergoing hip fracture surgery. Limited clinical data from a non-interventional study are available for patients undergoing fracture related surgery of the lower limbs such as hip fracture surgery hence its use is not recommended in these patients. Xarelto should be used with caution in patients with an increased bleeding risk when neuraxial anaesthesia or spinal/epidural puncture is administered. An epidural catheter should not be withdrawn earlier than 18 hours after the last administration of Xarelto. Xarelto should be administered at earliest 6 hours after the removal of the catheter. If traumatic puncture occurs the administration of Xarelto should be delayed for 24 hours. If an invasive procedure or surgical intervention is required, Xarelto 10 mg should be stopped at least 24 hours, if possible and based on clinical judgment of the physician. Xarelto should be used in women of childbearing potential only with effective contraception. Safety and efficacy have not been established in children and adolescents below 18 years. Xarelto is not recommended for patients with a history of thrombosis who are diagnosed with antiphospholipid syndrome and are persistently triple positive (for lupus anticoagulant, anticardiolipin antibodies, and anti–beta 2-glycoprotein I antibodies) as treatment with rivaroxaban is associated with an increased rate of recurrent thrombotic events compared with vitamin K antagonists (VKA). Undesirable effects: Common: Anemia, Eye hemorrhage, Gingival bleeding, Gastrointestinal tract hemorrhage (incl. rectal hemorrhage) Gastrointestinal and abdominal pains Dyspepsia Nausea Constipation & Diarrhea, Fever, Edema peripheral, Decreased general strength and energy, Vomiting, Postprocedural hemorrhage (incl. postoperative anemia and wound hemorrhage) Contusion, Increase in transaminases Pain in extremity Dizziness Headache Syncope, Urogenital tract hemorrhage Renal impairment (incl. blood creatinine increased, blood urea increased, Epistaxis,Hemoptysis Pruritus (incl. uncommon cases of generalized pruritus) Rash Ecchymosis Cutaneous and subcutaneous hemorrhage, Hypotension, Haematoma. For full listing of undesirable effects, please refer to the full product insert. For further prescribing information, please contact Bayer Zydus Pharma Private Limited, Bayer House, Central Avenue, Hiranandani Estate, Thane, Maharashtra, India Pin-400607. Email: medicalinfo.india@bayerzuspharma.com. Source: Version No. XA_2022_02 dated 21 Oct 2022 Based on CCDS version 14 and 17 dated 13 Jul 2022 and Patient counselling information from CCPI version 15 dated 01 Dec 2020 Rev date: Oct 2022