

About Venous Thromboembolism (VTE)



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Venous thromboembolism (VTE) is the most common, avoidable cause of hospital death¹.

- ◆ The worldwide incidence of VTE is 1 per 1000²
- ◆ In the EU, more than twice as many people die from VTE than from breast cancer, prostate cancer, AIDS and traffic accidents combined³



VTE Encompasses Two Serious Conditions:

Deep vein thrombosis (DVT) is a blood clot that forms in the veins that lie deep within the muscles, usually in the leg or pelvis. If all or part of the DVT breaks off and the blood clot moves to block a vessel in the lungs, it is known as a **pulmonary embolism (PE)**⁶, which can be rapidly fatal.

Symptoms of DVT include:

Pain, swelling, redness of the area, and dilation of the surface veins. The skin may also be warm to the touch

Symptoms of PE include:

Acute shortness of breath, chest pain, and rapid heart rate; some people may also cough blood

Deep vein thrombosis (DVT)

- ◆ Even in the absence of a PE, DVT alone can have burdensome and costly consequences such as post-thrombotic syndrome⁷
- ◆ The rate of VTE recurrence remains high, with hospital readmission for DVT at 19%⁸

Pulmonary embolism (PE)

- ◆ About 1 in 10 deaths that occur in the hospital is caused by pulmonary emboli¹¹
- ◆ 10–25% of PEs are rapidly fatal¹², usually within 2 hours of the onset of symptoms¹³. Without effective treatment PE can reoccur, and if it does, it is usually fatal¹⁴

Annual estimated incidence of DVT



Annual estimated incidence of acute PE



VTE can be difficult to diagnose, as up to half of patients have no specific symptoms

Who is at Risk of VTE?

- ◆ Patients undergoing major orthopaedic surgery for hip or knee replacement or major surgery for cancer
 - Without preventative treatment, the absolute DVT risk after hip or knee surgery is between 40% and 60%¹
- ◆ Patient-related, predisposing risk factors include inherited thrombophilia, advanced age, obesity, prior VTE and varicose veins¹
- ◆ Patients admitted to hospital for an acute medical condition

Economic Burden

- The complications associated with VTE, and its treatment, are frequent and costly. The main drivers of these VTE costs are initial and recurrent events requiring hospitalisation.
- ◆ In Europe, the annual cost of managing all-cause VTE has been estimated at approximately €4,000 per patient¹⁵



VTE Prevention and Treatment

Anticoagulants are the cornerstone of therapy for prevention of potentially deadly blood clots, but widely used traditional therapies are associated with significant drawbacks that challenge optimal patient treatment.

- ◆ The traditional standard therapy for **prevention of VTE** associated with orthopaedic surgery is a class of injectable anticoagulant drugs known as low molecular weight heparins (LMWH)
- ◆ The traditional standard of care for **treatment of VTE** and long-term prevention is the complex dual-drug approach of daily injections of LMWH followed by a transition to long-term oral therapy with a vitamin K antagonist (VKA), such as warfarin. As well as the difficulties associated with LMWH, managing patients on VKAs such as warfarin can also be challenging

Limitations of current VTE therapies may contribute to their under-utilisation¹⁶, creating challenges for patients and leaving them at risk.

Novel oral anticoagulants (OACs) can overcome the limitations of traditional anticoagulants to prevent and or treat venous and arterial thromboembolic (VAT) conditions.

Benefits of novel OACs include¹⁷:

- Predictable anticoagulation without the need for routine coagulation monitoring or frequent dose adjustment
- Low risk of drug-drug interactions
- No significant food interactions

Xarelto® (rivaroxaban) is approved to protect patients from blood clots across more venous conditions than any other novel oral anticoagulant

VTE Treatment and Recurrent Prevention: For adult patients with DVT and PE, 'Xarelto' is the first single-drug solution and the only novel OAC approved for acute treatment and the prevention of recurrent VTE.

- ◆ **DVT:** As a single-drug solution, 'Xarelto' is highly effective in providing simplified patient management from hospital to home^{17,18,19}. Additionally 'Xarelto' has a similar low rate of major bleeding compared with the dual-drug approach of LMWH and VKA¹⁸.
- ◆ **PE:** As a single-drug solution, 'Xarelto' is highly effective in protecting against life-threatening PEs without the need for injections or routine coagulation monitoring^{17,18,19}. Additionally 'Xarelto' significantly lowers the risk of major bleeding compared with the dual-drug approach of LMWH and VKA¹⁹.

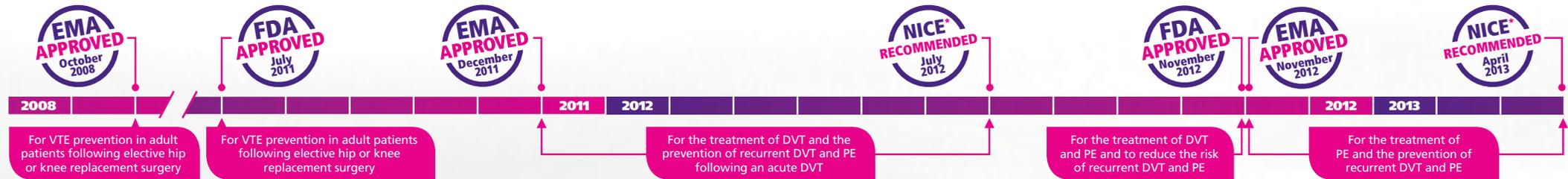


VTE Prevention in Adult Patients Following Elective Hip or Knee Replacement Surgery: For adult patients who have had major orthopaedic surgery, one 10 mg tablet, once-daily 'Xarelto' provides superior protection against VTE with similar safety compared to the LMWH enoxaparin^{17,20,21,22}. Patients on 'Xarelto' also experience fewer symptomatic VTEs and fewer bleeding complications post-surgery, resulting in shorter hospital stays^{23,24}.

About Venous Thromboembolism (VTE) continued...



'Xarelto' VTE Regulatory Milestones



*UK's NICE issued Final Guidance in July 2012 recommending 'Xarelto' for National Health Service (NHS) use for the treatment of DVT and the prevention of recurrent DVT and PE following an acute DVT in adults. In April 2013 NICE also issued Final Guidance recommending 'Xarelto' for NHS use for the treatment of PE and the prevention of recurrent DVT and PE. The positive NICE appraisals were based on detailed analysis of the clinical and cost-effectiveness benefits of 'Xarelto' ^{25,26}

About 'Xarelto'

Rivaroxaban is the most broadly indicated novel oral anticoagulant and is marketed under the brand name Xarelto®. To date, 'Xarelto' is approved for five indications across seven distinct areas of use, consistently protecting patients across more venous and arterial thromboembolic (VAT) conditions than any other novel OAC:

 The prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation (AF) with one or more risk factors	 The treatment of deep vein thrombosis (DVT) in adults	 The treatment of pulmonary embolism (PE) in adults	 The prevention of recurrent DVT and PE in adults
 The prevention of venous thromboembolism (VTE) in adult patients undergoing elective hip replacement surgery	 The prevention of venous thromboembolism (VTE) in adult patients undergoing elective knee replacement surgery	 The prevention of atherothrombotic events (cardiovascular death, heart attack or stroke) after an Acute Coronary Syndrome in adult patients with elevated cardiac biomarkers when co-administered with acetylsalicylic acid (ASA) alone or with ASA plus a thienopyridine (clopidogrel or ticlopidine)	

Whilst licences may differ from country to country, across all indications 'Xarelto' is approved in more than **120 countries**.

Rivaroxaban was discovered by Bayer HealthCare, and is being jointly developed with Janssen Research & Development, LLC. 'Xarelto' is marketed outside the U.S. by Bayer HealthCare and in the U.S. by Janssen Pharmaceuticals, Inc. (a Johnson & Johnson Company).

Anticoagulant medicines are potent therapies used to prevent or treat serious illnesses and potentially life threatening conditions. Before initiating therapy with anticoagulant medicines, physicians should carefully assess the benefit and risk for the individual patient.

Responsible use of 'Xarelto' is a very high priority for Bayer, and the company has developed a **Prescribers Guide** for physicians and a **'Xarelto' Patient Card** for patients to support best practice. To learn more, please visit: <https://prescribe.xarelto.com>.

To learn more about thrombosis, please visit www.thrombosisadviser.com

To learn more about VAT, please visit www.VATspace.com

To learn more about 'Xarelto', please visit www.xarelto.com

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