



About Xarelto[®] (Rivaroxaban)

What is Xarelto[®] (Rivaroxaban)?

'Xarelto' is a highly effective, oral anticoagulant developed to prevent and treat dangerous blood clots in a wide range of patients with or at threat from venous or arterial blood clots. 'Xarelto' has the potential to improve clinical outcomes and quality of life for a wide range of patients with, or at risk of thromboembolism in a broad range of clinical settings.

What is 'Xarelto' Approved for?

'Xarelto' is currently approved in more than 110 countries worldwide for the prevention of venous thromboembolism (VTE) in adult patients undergoing total elective hip or knee replacement surgery. It is marketed outside the U.S. by Bayer HealthCare in this indication. In the U.S., Janssen Pharmaceuticals, Inc. (a Johnson & Johnson Company) holds marketing rights. In November 2011, 'Xarelto' was also approved by the US Food and Drug Administration (FDA) to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation (AF).


In September 2011, 'Xarelto' was recommended for European approval by the European Committee for Medicinal Products for Human Use (CHMP) for the prevention of stroke and systemic embolism in adult patients with non-valvular AF, as well as for the treatment of deep vein thrombosis (DVT) and prevention of recurrent DVT and pulmonary embolism (PE) following an acute DVT in adults.

How Does 'Xarelto' Work?

'Xarelto' is the first oral direct and highly selective inhibitor of Factor Xa, an enzyme which acts at a pivotal point in the blood-clotting (coagulation) process.

- ◆ Coagulation requires a complex series of chemical reactions and body signals. This process of chemical reactions is often referred to as the 'Clotting Cascade'. One of the many clotting factors (blood clot proteins) is Factor Xa. Factor Xa is needed to produce thrombin that promotes the formation of blood clots. One molecule of Factor Xa catalyses the formation of approximately 1,000 thrombin molecules via what is known as a 'thrombin burst'^{1,2}



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- ◆ Directly targeting and inhibiting Factor Xa prevents the thrombin burst. Selectivity to Factor Xa has been proven to be clinically meaningful. Studies have demonstrated an increase in the anticoagulant efficacy of heparin-based drugs as their selectivity for Factor Xa increases¹

What are the Benefits of 'Xarelto'?

New oral anticoagulants hold the promise of overcoming the limitations of traditional anticoagulants, thereby enabling their use to prevent and or treat more venous and arterial thromboembolic (VAT) conditions.

Benefits of 'Xarelto' include oral administration, predictable anticoagulation without the need for routine coagulation monitoring or frequent dose adjustment, low risk of drug-drug interactions and no dietary restrictions.

'Xarelto' has demonstrated clinical benefit in comparison to standard therapy in a broad range of indications.

The Clinical Trial Programme for 'Xarelto'

More than 75,000 patients have taken part in the 'Xarelto' clinical development programme so far, evaluating the product in the prevention and treatment of a broad range of VAT conditions, including:

- ◆ Prevention of VTE in adult patients undergoing total elective hip or knee replacement surgery
- ◆ Treatment of DVT and PE, and prevention of recurrent DVT and PE
- ◆ Prevention of stroke and systemic embolism in patients with AF
- ◆ Prevention of VTE in acutely ill, hospitalised patients
- ◆ Secondary prevention of acute coronary syndrome (ACS)

The extensive clinical trial programme supporting 'Xarelto' makes it the most studied and widely published new oral anticoagulant in the world today.





References

- 1) Turpie AG. Oral, direct factor Xa inhibitors in development for the prevention and treatment of thromboembolic diseases. *Arterioscler.Thromb.Vasc.Biol.* 2007;27,(6)1238-1247
- 2) Mann KG, Brummel K, & Butenas S. What is all that thrombin for? *J.Thromb.Haemost.* 2003;1,(7)1504-151

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

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