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Xarelto advertisement.

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New oral, once daily Xarelto® Simply raising the standard in VTE prevention

SUPERIOR EFFICACY in elective
hip or knee replacement surgery
vs. enoxaparin^{1,2}

FAVOURABLE SAFETY PROFILE
with comparable bleeding rates
to enoxaparin¹⁻³

SIMPLE DOSING –
One tablet. One dose. Once a day.⁴

NEW First in ORAL, Direct Factor Xa Inhibition



Xarelto®
rivaroxaban

Simple, convenient clot prevention

References:

1. Eriksson BI et al. *N Engl J Med* 2008; **358**: 2765-75. (RECORD1)
2. Lassen MR et al. *N Engl J Med* 2008; **358**: 2776-86. (RECORD3)
3. Kakkar AK et al. *Lancet* 2008; **372**: 31-9. (RECORD2)
4. Xarelto SmPC, September 2008.

Xarelto® 10 mg film-coated tablets (rivaroxaban)
Prescribing Information

(Refer to full Summary of Product Characteristics (SmPC) before prescribing) **Xarelto® 10 mg film-coated tablets.**
Presentation: Light red, round, film-coated tablets containing 10 mg rivaroxaban. **Indication:** Prevention of venous thromboembolism (VTE) in adult patients undergoing elective hip or knee replacement surgery. **Posology and method of administration:** Dosage 10 mg rivaroxaban orally once daily with or without food; initial dose should be taken 6 to 10 hours after surgery provided haemostasis established. **Recommended treatment duration:** Dependent on individual risk of patient for VTE determined by type of orthopaedic surgery: for major hip surgery 5 weeks; for major knee surgery 2 weeks. **Renal & Hepatic impairment:** see Warnings and precautions. **Patients above 65 years, Body weight & Gender:** No dose adjustment. **Children and adolescents:** Not recommended below 18 years of age. **Contraindications:** Hypersensitivity to active

substance or any excipient; clinically significant active bleeding; hepatic disease associated with coagulopathy and clinically relevant bleeding risk; pregnancy and lactation. **Warnings and precautions:** Treatment with rivaroxaban not recommended in patients: undergoing hip fracture surgery; receiving concomitant systemic treatment with strong CYP3A4 and P-gp inhibitors, i.e. azole-antimycotics (e.g. ketoconazole, itraconazole, voriconazole & posaconazole; fluconazole can be used with caution – see below) or HIV protease inhibitors (e.g. ritonavir); with severe renal impairment (creatinine clearance <15 ml/min); below 18 years of age. The following are at increased risk of bleeding – monitor carefully for bleeding complications after treatment initiation: patients with severe renal impairment (creatinine clearance 15-29 ml/min); patients with moderate renal impairment (creatinine clearance 30-49 ml/min) concomitantly receiving other medicinal products which increase rivaroxaban plasma concentrations; cirrhotic patients with moderate hepatic impairment (Child Pugh B) not associated with coagulopathy; patients treated concomitantly with medicinal products affecting haemostasis (e.g. NSAIDs, acetylsalicylic acid, platelet aggregation inhibitors, other antithrombotic agents) or with the moderate concurrent CYP3A4 and P-gp inhibitor fluconazole; patients with

congenital or acquired bleeding disorders; uncontrolled severe arterial hypertension; active ulcerative gastrointestinal disease; recent gastrointestinal ulcerations; vascular retinopathy; recent intracranial or intracerebral haemorrhage; intraspinal or intracerebral vascular abnormalities; recent brain, spinal or ophthalmological surgery. Strong CYP3A4 inducers (e.g. rifampicin, phenytoin, carbamazepine, phenobarbital or St. John's Wort) should be used with caution since they may reduce rivaroxaban plasma concentrations and hence efficacy. Take special care when neuraxial anaesthesia or spinal/epidural puncture is employed. Xarelto contains lactose. **Interactions:** see Warnings and precautions. **Pregnancy and lactation:** Contraindicated. **Effects on ability to drive and use machines:** No studies performed. Syncope and dizziness uncommon post-operatively but may affect ability to drive and use machines. In these cases, patients should not drive or use machines. **Undesirable effects: Common** - increased GGT, increase in transaminases (incl. increased ALT, AST), anaemia (incl. respective laboratory parameter), nausea, post-procedural haemorrhage (incl. post-operative anaemia & wound haemorrhage) **Less frequent serious side effects** – increase in: lipase, amylase, blood bilirubin, LDH, alkaline phosphatase; tachycardia, thrombocythaemia, syncope, renal impairment (incl.

increased blood creatinine/urea), any form of haemorrhage, hypersensitivity, abnormal hepatic function, hypotension. Prescribers should consult SmPC in relation to other side effects. **Legal Category:** POM. **Package Quantities/Basic NHS Costs:** 10 tablets: £45.00, 30 tablets: £135.00 and 100 tablets: £450.00 **MA Number(s):** EU/1/08/472/001-8 **Further information available from:** Bayer Schering Pharma, Bayer plc, Bayer House, Strawberry Hill, Newbury, Berkshire RG14 1JA, U.K. Telephone: 01635 563000. **Date of preparation:** September 2008

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Adverse events should be reported.
Reporting forms and information can be found at www.yellowcard.gov.uk
Adverse events should also be reported to Bayer Schering Pharma; Tel: 01635 563500, Fax: 01635 563703 Email: phdsguk@bayer.co.uk