

הודעה על החמרה (מידע בטיחות) בעלון לרופא

תאריך 4.4.13

שם תכשיר באנגלית ומספר הרישום Xarelto 15mg (147-44-33576-00/01)

שם בעל הרישום Bayer Israel Ltd.

טופס זה מיועד לפרוט ההחמרות בלבד !

ההחמרות המבוקשות		
פרק בעלון	טקסט נוכחי	טקסט חדש
Contraindications	<p>Hypersensitivity to the active substance or to any of the excipients.</p> <p>Clinically significant active bleeding.</p> <p>Hepatic disease associated with coagulopathy and clinically relevant bleeding risk including cirrhotic patients with Child Pugh B and C (see section 5.2).</p> <p>Pregnancy and breast feeding (see section 4.6).</p>	<p>Hypersensitivity to the active substance or to any of the excipients listed in section 6.1. Clinically significant active bleeding.</p> <p><u>Lesion or condition at significant risk of major bleeding such as current or recent gastrointestinal ulceration, presence of malignant neoplasms at high risk of bleeding, recent brain or spinal injury, recent brain, spinal or ophthalmic surgery, recent intracranial haemorrhage, known or suspected oesophageal varices, arteriovenous malformations, vascular aneurysms or major intraspinal or intracerebral vascular abnormalities.</u></p> <p><u>Concomitant treatment with any other anticoagulant agent e.g. unfractionated heparin (UFH), low molecular weight heparins (enoxaparin, dalteparin, etc.), heparin derivatives (fondaparinux, etc.), oral anticoagulants (warfarin, apixaban, dabigatran, etc.) except under the circumstances of switching therapy to or from rivaroxaban (see section 4.2) or when UFH is given at doses necessary to maintain a patent central venous or arterial catheter.</u></p> <p>Hepatic disease associated with coagulopathy and clinically relevant bleeding risk including cirrhotic patients with Child Pugh B and C (see section 5.2).</p> <p>Pregnancy and breast feeding (see section 4.6).</p>

<p>Special populations</p> <p>- For the treatment of DVT, <u>treatment of PE</u> and prevention of recurrent DVT and PE: Patients should be treated with 15 mg twice daily for the first 3 weeks. Thereafter, the recommended dose is 45 <u>20 mg once daily based on PK modelling (see sections 4.4 and 5.2). A reduction of the dose from 20 mg once daily to 15 mg once daily should be considered if the patient's assessed risk for bleeding outweighs the risk for recurrent DVT and PE. The recommendation for the use of 15 mg is based on PK modelling and has not been studied in this clinical setting(see sections 4.4, 5.1 and 5.2).</u></p> <p>-</p>	<p>- For the treatment of DVT and prevention of recurrent DVT and PE: Patients should be treated with 15 mg twice daily for the first 3 weeks. Thereafter, the recommended dose is 15 mg once daily based on PK modelling (see sections 4.4 and 5.2).</p>	<p>Posology, Dosage & administration</p>
<p><u>Haemorrhagic risk</u></p> <p><u>As with other anticoagulants, patients taking Xarelto are to be carefully observed for signs of bleeding. It is recommended to be used with caution in conditions with increased risk of haemorrhage. Xarelto administration should be discontinued if severe haemorrhage occurs.</u></p> <p>In the clinical studies mucosal bleedings (i.e. epistaxis, gingival, gastrointestinal, genito urinary) and anaemia were seen more frequently during long term rivaroxaban treatment compared with VKA treatment. Thus, in addition to adequate clinical surveillance, laboratory testing of haemoglobin/haematocrit could be of value to detect occult bleeding, as judged to be appropriate.</p> <p>Several sub-groups of patients, as detailed below, are at increased risk of bleeding.</p> <p>These patients are to be carefully monitored for signs and symptoms of bleeding complications and anaemia after initiation of treatment (see section 4.8). Any unexplained fall in haemoglobin or blood pressure should lead to a search for a bleeding site.</p>	<p>Haemorrhagic risk</p> <p>In the clinical studies mucosal bleedings (i.e. epistaxis, gingival, gastrointestinal, genito urinary) and anemia were seen more frequently during long term rivaroxaban treatment compared with VKA treatment. Thus, in addition to adequate clinical surveillance, laboratory testing of haemoglobin/haematocrit could be of value to detect occult bleeding, as judged to be appropriate.</p> <p>Several sub-groups of patients, as detailed below, are at increased risk of bleeding. These patients are to be carefully monitored for signs and symptoms of bleeding complications and anaemia after initiation of treatment (see section 4.8). Any unexplained fall in haemoglobin or blood pressure should lead to a search for a bleeding site.</p>	<p>Special Warnings and Special Precautions for Use</p>

<p>Although treatment with rivaroxaban does not require routine monitoring of exposure, rivaroxaban levels measured with a calibrated quantitative anti-Factor Xa assay may be useful in exceptional situations where knowledge of rivaroxaban exposure may help to inform clinical decisions, e.g., overdose and emergency surgery (see sections 5.1 and 5.2).</p> <p><u>Other haemorrhagic risk factors</u></p> <ul style="list-style-type: none">• 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• bronchiectasis or history of pulmonary bleeding. <p>There is no need for monitoring of coagulation parameters during treatment with rivaroxaban in clinical routine. However, if clinically indicated rivaroxaban levels can be measured by calibrated quantitative anti-Factor Xa tests (see section 5.1 and 5.2).</p> <p><u>Patients with prosthetic valves</u></p> <p>Safety and efficacy of Xarelto have not been studied in patients with prosthetic heart valves; therefore, there are no data to support that Xarelto 20 mg (15 mg in patients with moderate or severe renal impairment) provides adequate anticoagulation in this patient population. Treatment with Xarelto is not recommended for these patients.</p>	<p>Other haemorrhagic risk factors</p> <ul style="list-style-type: none">• 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• bronchiectasis or history of pulmonary bleeding. <p>Patients with prosthetic valves</p> <p>Safety and efficacy of Xarelto have not been studied in patients with prosthetic heart valves; therefore, there are no data to support that Xarelto 20 mg (15 mg in patients with moderate or severe renal impairment) provides adequate anticoagulation in this patient population. Treatment with Xarelto is not recommended for these patients.</p>	
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<p>Haemodynamically unstable PE patients or patients who require thrombolysis or pulmonary embolectomy</p> <p>Xarelto is not recommended as an alternative to unfractionated heparin in patients with pulmonary embolism who are haemodynamically unstable or may receive thrombolysis or pulmonary embolectomy since the safety and efficacy of Xarelto have not been established in these clinical situations.</p> <p>Patients with acute pulmonary embolism</p> <p>Xarelto is not recommended in the treatment of acute pulmonary embolism.</p>		
<p>Common: Syncope, Tachycardia, haemoptysis, Gingival bleeding, gastrointestinal tract haemorrhage (incl. gingival bleeding and rectal haemorrhage), cutaneous and subcutaneous haemorrhage renal impairment (incl. blood creatinine increased, blood urea increased) wound secretion</p> <p>Uncommon: syncope, Tachycardia, Haemoptysis, cutaneous and subcutaneous haemorrhage, Renal impairment (incl. blood creatinine increased, blood urea increased) localised oedema, Wound secretion</p> <p>Rare: localised oedema, Vascular pseudoaneurysm</p>	<p>Common: syncope, Tachycardia, Gastrointestinal, tract haemorrhage (incl. gingival bleeding and rectal haemorrhage)</p> <p>Uncommon: Haemoptysis, cutaneous and subcutaneous haemorrhage, Renal impairment (incl. blood creatinine increased, blood urea increased), localised oedema, Wound secretion</p>	<p>Adverse events</p>