הודעה על החמרה (מידע בטיחות) בעלון לרופא

(מעודכן 05.2013)

תאריך _18.11.2013_

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

Xarelto 20 mg- 147-45-33579-00/01

שם בעל הרישום. Bayer Israel Ltd

טופס זה מיועד לפרוט ההחמרות בלבד !

ההחמרות המבוקשות		
טקסט חדש	**טקסט נוכחי**	**פרק בעלון**
WARNING: (A) PREMATURE DISCONTINUATION OF XARELTO INCREASES THE RISK OF THROMBOTIC EVENTS , (B) SPINAL/EPIDURAL HEMATOMA A. PREMATURE DISCONTINUATION OF XARELTO INCREASES THE RISK OF THROMBOTIC EVENTS Premature discontinuation of any oral anticoagulant, including XARELTO, increases the risk of thrombotic events. If anticoagulation with XARELTO is discontinued for a reason other than pathological bleeding or completion of a course of therapy, consider coverage with another anticoagulant [see posology and method of administration (4.2), and special warnings and precautions for use(4.4)] B. SPINAL/EPIDURAL HEMATOMA Epidural or spinal hematomas have occurred in patients treated with XARELTO who are receiving neuraxial anesthesia or undergoing spinal puncture. These hematomas may result in long-term or permanent paralysis. Consider these risks when scheduling patients for spinal procedures. Factors that can increase the risk of developing epidural or spinal hematomas in these patients include: • use of indwelling epidural catheters • concomitant use of other drugs that affect hemostasis, such as non-steroidal anti inflammatory drugs (NSAIDs), platelet inhibitors, other anticoagulants • a history of traumatic or repeated epidural or spinal punctures • a history of spinal deformity or spinal surgery [see special warnings and precautions for use (4.4)].		**Warning Box**

Monitor patients frequently for signs and symptoms of neurological impairment. If neurological compromise is noted, urgent treatment is necessary [see Warnings and Precautions (4.4)]. Consider the benefits and risks before neuraxial intervention in patients anticoagulated or to be anticoagulated for thromboprophylaxis [see Warnings and Precautions (4.4)].		
Spinal/epidural anaesthesia or puncture When neuraxial anaesthesia (spinal/epidural anaesthesia) or spinal/epidural puncture is employed, patients treated with antithrombotic agents for prevention of thromboembolic complications are at risk of developing an epidural or spinal haematoma which can result in long-term or permanent paralysis [See boxed warning]. An epidural catheter should not be removed earlier than 18 hours after the last administration of rivaroxaban. The next rivaroxaban dose is not to be administered earlier than 6 hours after the removal of the catheter. If traumatic puncture occurs the administration of rivaroxaban is to be delayed for 24 hours. Elderly population Increasing age may increase haemorrhagic risk (see section 5.2). Increased Risk of Thrombotic Events after Premature Discontinuation Premature discontinuation of any oral anticoagulant, including Xarelto, in the absence of adequate alternative anticoagulation increases the risk of thrombotic events. An increased rate of stroke was observed during the transition from Xarelto to warfarin in clinical trials in atrial fibrillation patients. If Xarelto is discontinued for a reason other than pathological bleeding or completion of a course of therapy, consider coverage with another anticoagulant [for conversion instructions see Dosage and Administration (4.2)]		**Special Warnings and Special Precautions for Use**