Bayer HealthCare

14 Dec 2015

The new oral anticoagulants (NOACs) including Xarelto® (Rivaroxaban) Beware of the risk factors for bleeding pay attention to posology, contraindications, and warnings and precautions for use to reduce the risk of bleeding

Dear Health Care Provider,

Bayer (LLC) Saudi Arabia, would like to inform you about the risk of All NOACs including Xarelto® (Rivaroxaban). The new oral anticoagulants in recent years have been authorised for indications where vitamin K antagonists (warfarin, phenprocoumon and acenocoumarol) or low molecular weight heparins (LMWH) have been used for decades.

Xarelto® (Rivaroxaban) has been approved in Saudi Arabia for the,

- Prevention of venous thromboembolism (VTE) in adult patients undergoing elective hip or knee replacement surgery.
- Prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation with one or more risk factors, such as congestive heart failure, hypertension, age ≥ 75 years, diabetes mellitus, prior stroke or transient ischaemic attack.
- Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT and PE in adults.

Unlike vitamin K antagonists, there is no need for routine monitoring of anticoagulant activity when administering these new medicines.

However, clinical trials and post-marketing experience have shown that major bleeding events, including events leading to death, are not confined to vitamin K antagonists/LMWH but are also significant risks for the new oral anticoagulants. Furthermore, post-marketing reports indicate that not all prescribers are sufficiently aware of the product information in terms of managing bleeding risks.

The information provided in this letter has been reviewed and endorsed by the Saudi Food and Drug Authority (SFDA) and this letter is distributed upon request of the National Pharmacovigilance and Drug Safety Center.

Recommendations

In light of the above, prescribers should consider the individual patient risk of bleeding and observe posology, contraindications, and warnings and precautions for use. While differences in contraindications exist between the new oral anticoagulants, they share the following contraindications:

- Active clinically significant bleeding.
- Lesion or condition, if considered a significant risk factor for major bleeding. This may include 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.
- 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, other) except under the circumstances of switching therapy to or from the medicine, or when UFH is given at doses necessary to maintain an open central venous or arterial catheter.

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Please refer to the respective product information for All NOACs Including Xarelto® (enclosed) for information about additional contraindications specific to each medicine.

It is important to pay attention to the recommended posology and the warnings and precautions for use to minimise the risk of bleeding. This includes a careful benefit-risk assessment in patients with lesions, conditions, procedures and/or treatment (such as NSAIDs and antiplatelets), which increase the risk of major bleeding. In addition, clinical surveillance for signs and symptoms of bleedings is recommended throughout the treatment period, particularly in patients at increased risk of bleeding.

Attention should also be paid to renal function. Renal impairment may constitute a contraindication or a reason to consider not using the medicines or reducing their dose. Please refer to the product information since recommendations differ between All NOACs medicines.

There is currently no specific antidote available for Xarelto®. The product information for each product includes advice on treatment in the event of bleeding complications.

The information in this letter has been approved by the Saudi Food and Drug Authority.

Call for reporting

As a reminder, there is a need to report any suspected adverse reactions to the National Pharmacovigilance and Drug Safety Center (NPC):

- Fax: +966-11-205-7662
- Call NPC at +966-11-2038222, Ext: 2317-2356-2353-2354-2334-2340.
- Toll free phone: 8002490000
- E-mail: npc.drug@sfda.gov.sa
- Website: www.sfda.gov.sa/npc

Or

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Yours Sincerely,

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Abdullah Rajkhan
Pharmacovigilance Country Head, KSA and GCC