SAFERx
SAFER USE OF HIGH RISK MEDICINES

Waitemata District Health Board
Best Care for Everyone

RIVAROXABAN - SAFE PRESCRIBING - BE BLEEDING CAREFUL

- CHECK AND MONITOR RENAL AND HEPATIC FUNCTION
- DO NOT USE DURING PREGNANCY
- ASSESS AND INFORM PATIENTS ABOUT BLEEDING RISK
- MAKE SURE PATIENTS KNOW ABOUT SAFE STORAGE AND ADMINISTRATION

Rivaroxaban is indicated for the prophylaxis of venous thromboembolism (VTE) following elective hip or knee replacement surgery, for the prophylaxis of recurrent deep vein thrombosis (DVT) and pulmonary embolism (PE), and for the treatment of DVT or PE. It is also indicated for the prophylaxis of stroke and systemic embolism in patients with non-valvular atrial fibrillation (AF) who are considered high-risk.

Rivaroxaban is contraindicated in patients with mechanical prosthetic valves.

CHECK AND MONITOR RENAL AND HEPATIC FUNCTION

Rivaroxaban exposure is inversely correlated to a decrease in renal function. Therefore, before initiating treatment with rivaroxaban, it is important that any degree of renal impairment is accurately determined.

Renal impairment

Rivaroxaban is contraindicated in patients with creatinine clearance (CrCl) less than 15 mL/min or undergoing dialysis.

For patients with CrCl less than 30mL/min, other agents should be considered due to the increased risk of bleeding.

For patients with moderate renal impairment, CrCl between 30-49mL/min, rivaroxaban may be used, however dose adjustments may be required. Make sure the patient is aware that there could be an increased risk of bleeding and to seek medical care if bleeding occurs.

The dose of rivaroxaban should be adjusted to accommodate for renal function.

Table 1. Recommended doses of rivaroxaban

<table>
<tr><th>Creatinine clearance and indication</th><th>VTE prevention (THJR and TKJR)*</th><th>Stroke prevention in non-valvular AF</th><th>DVT treatment; prevention of recurrent DVT and PE</th></tr>
<tr><td>>50mL/min</td><td rowspan="2">10mg daily</td><td>20mg daily</td><td rowspan="2">15mg twice daily for three weeks,
then 20mg once daily</td></tr>
<tr><td>30-49mL/min</td><td>15mg daily</td></tr>
<tr><td>15-29mL/min</td><td>10mg daily
(with caution)</td><td colspan="2">Contraindicated</td></tr>
<tr><td>< 15mL/min</td><td colspan="3">Contraindicated</td></tr>
</table>

*Total Hip Joint Replacement – recommended duration of treatment is 5 weeks, starting 6-10 hours after surgery

*Total Knee Joint Replacement – recommended duration of treatment is 2 weeks, starting 6-10 hours after surgery

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https://itunes.apple.com/nz/developer/healthobs-ltd/id498413740

Hepatic impairment

For patients with moderate to severe hepatic impairment (Child-Pugh B and C, see the full version on www.saferx.co.nz for explanation), rivaroxaban is contraindicated due to the increased bleeding risk.

Although there is no specific dose adjustment required for the elderly, increasing age may be associated with declining renal and hepatic function so rivaroxaban should be used with caution. Rivaroxaban is not recommended in those under 18 years due to a lack of available data.

➥ continued

RIVAROXABAN

DO NOT USE DURING PREGNANCY

Rivaroxaban is contraindicated during pregnancy. Inform women of childbearing potential that effective contraception should be used.

Rivaroxaban is contraindicated during breast-feeding.

ASSESS AND INFORM PATIENTS ABOUT BLEEDING RISK

Patients should inform their doctor if they experience any nose bleeds, blood in the urine or stools or cough up blood. It is generally advisable to delay the next administration until they have been assessed.

Patients should let their dentist know they are taking an anticoagulant; if an invasive procedure or surgical intervention is required, rivaroxaban may need to be withheld.

The bleeding risk is increased when rivaroxaban is used concomitantly with other anticoagulants. For patients taking concurrent antiplatelet therapy (eg clopidogrel, aspirin), a careful risk-benefit assessment should be performed. All NSAIDs increase the risk of bleeding so concurrent use with rivaroxaban might possibly increase this risk. Caution should be used and patients advised to watch out for bruising or prolonged bleeding.

Medicines that can increase rivaroxaban plasma concentrations eg itraconazole and ritonavir. Some anticonvulsants (eg phenytoin, carbamazepine)or St. John's Wort may decrease the anticoagulant effect of rivaroxaban.

MAKE SURE PATIENTS KNOW ABOUT SAFE STORAGE AND ADMINISTRATION

Emphasise to patients that rivaroxaban is an anticoagulant, and overdose or unintended use can lead to fatal haemorrhagic complications .The effect of rivaroxaban is irreversible, a specific antidote is not available in NZ and vitamin K will not affect the anticoagulant activity.

Due to its high degree of plasma protein binding, rivaroxaban cannot be removed by dialysis.

For these reasons, it is important that rivaroxaban is kept out of reach and out of sight of children, and it must not be shared with others.

Although direct oral anticoagulants such as rivaroxaban do not require monitoring of their anticoagulant effect and interact with fewer foods and medicines compared with warfarin, adherence cannot be easily measured.

Switching to rivaroxaban

If the patient is already taking warfarin or another vitamin K antagonist, it should be stopped, and rivaroxaban should only be started once the INR is below 2.5 (or 3, depending on the indication). Refer to the data sheet for more detailed information about switching between anticoagulants.

ACKNOWLEDGEMENTS

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Key References

1. New Zealand Formulary; Rivaroxaban www.nzf.org.nz/nzf_1508.html (Accessed 27-09-18)
2. Bayer New Zealand Ltd. Xarelto®(rivaroxaban) Data Sheet. Dec 2017. www.medsafe.govt.nz/profs/datasheet/x/Xareltotab.pdf (Accessed 27-09-18)
3. Bayer New Zealand Ltd. Xarelto®(rivaroxaban) consumer medical information. October 2017. www.medsafe.govt.nz/consumers/cmi/x/xarelto.pdf (Accessed 27-09-18)

CLICK HERE FOR FURTHER INFORMATION ON RIVAROXABAN AND A FULL REFERENCE LIST

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