Barts Health NHS
NHS Trust

Rivaroxaban (Xarelto) counselling checklist

Patient Name: …… **Hospital Number:** …..……..
This patient has been counselled on the following issues regarding rivaroxaban therapy by a pharmacist, doctor or anticoagulant practitioner, in accordance with the guidance overleaf.

	Counselling points discussed	
1.	Indication for rivaroxaban	
2.	What an anticoagulant is and alternative anticoagulation options	
3.	Benefits and disadvantages of rivaroxaban compared to other anticoagulants	
4.	Expected duration of therapy - specify if known:	
5.	Basic mode of action	
6.	Dose	
7.	How to take: • Doses of 15mg or 20mg must be taken with food • Aim to take every day, at the same time of day Exploring barriers to taking medication	
8.	What to do if a dose is missed (Also: extra dose taken accidentally? Seek medical help)	
9.	Importance of taking it every day: • It is less effective if not taken daily • Ways of remembering to take the tablets e.g. calendar or smartphone alerts	
10.	Monitoring blood tests, how often it is needed and by whom	
11.	Side effects of rivaroxaban and what to do about them • Signs/symptoms of over-anticoagulation: bleeding or bruising • Small risk of recurrence of blood clots	
12.	Potential for drug interactions and the need to inform prescribers (including NSAIDs such as ibuprofen and aspirin)	
13.	Alcohol intake	
14.	Contraception, pregnancy, and hormone replacement therapy (if relevant)	
15.	Hobbies (including contact sports) and leisure activities	
16.	How to obtain further supplies of rivaroxaban	
17.	Hospitalisation, surgery, dental work and injections	
18.	Who to contact for advice/ further information	

Patient/advocate/representative:

Print name .....……..
Signature: …… Date: ……

Practitioner: (to counsel the patient and upload this completed document in patient electronic record or file in paper record)

Print name: ..... Bleep/ext: ……

Signature: ……..…… Date ……..

The patient must receive:

- **a copy of the first page of this completed document**
- **a rivaroxaban patient information booklet**
- **a patient alert card. The alert card MUST be fully completed and the patient advised to keep it with him/her at all times.**

General guidance on counselling points

Only provide information relevant to the patient

1.	Rivaroxaban is licensed for: (a) Prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation with one or more risk factors, such as: • prior stroke or transient ischaemic attack • age≥ 75 years • hypertension • diabetes mellitus • congestive heart failure (b) Treatment of deep-vein thrombosis (DVT) or pulmonary embolism (PE) (c) Prevention of recurrent DVT or PE (d) Prevention of DVT/PE in adult patients undergoing elective hip/knee replacements (e) Prevention of atherothrombosis following an acute coronary syndrome with elevated cardiac biomarkers (in combination with aspirin alone or aspirin and clopidogrel) (f) Prevention of atherothrombotic events in patients with coronary artery disease or symptomatic peripheral artery disease at high risk of ischaemic events (in combination with aspirin)
2.	Alternative anticoagulants: warfarin (and other oral vitamin K antagonists), low molecular weight heparin (LMWH), other direct oral anticoagulants (e.g. dabigatran, apixaban, edoxaban) • For AF, rivaroxaban was shown to be as effective as warfarin for the prevention of stroke and systemic embolism, with a similar rate of major bleeding, but with a lower risk of intracranial haemorrhage. There was a higher rate of GI bleeding with rivaroxaban compared to warfarin. • For the treatment of acute DVT/PE: rivaroxaban was shown to be as effective as enoxaparin followed by warfarin in preventing symptomatic recurrent DVT/PE.
3.	Advantages (vs. warfarin): fixed dose, no routine coagulation monitoring, more stable anticoagulation control, lower risk of intracranial haemorrhage (AF patients). Rivaroxaban's onset of action occurs within a few hours of taking the tablet, whereas warfarin's onset of action can take up to three days. Disadvantages (vs. warfarin): unable to routinely monitor coagulation but monitoring not usually required, limited long-term data. Rivaroxaban contains lactose from cow's milk, therefore not appropriate for patients with lactose intolerance. Disadvantage vs. apixaban, edoxaban: must take with food Advantage vs. apixaban: once daily dosing Advantage vs. dabigatran: smaller tablet, can be crushed or put in dossette box Disadvantage vs. dabigatran: no widely available direct antidote
4.	The duration of therapy is adjusted according to risk factors and is individualised after careful assessment of the treatment benefit against the risk for bleeding. Duration is usually long term for atrial fibrillation. Prevention of DVT/PE in adult patients undergoing elective hip replacement is 35 days. Prevention of DVT/PE in adult patients undergoing elective knee replacement is 14 days. Treatment of DVT/PE is variable depending on the site and cause of the thrombosis, and should be continued until review in thrombosis clinic. If unsure, check with doctor.
5.	Basic mode of action: belongs to a group of medicines called antithrombotic agents; blocks a blood clotting factor (factor Xa) and thus reduces the tendency of the blood to form clots.
6.	Dose: (a) Prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation with one or more risk factors, such as: prior stroke or transient ischaemic attack, age≥ 75 years, hypertension, diabetes mellitus, congestive heart failure: 20mg

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	once daily (b) Treatment of DVT/PE: 15mg twice daily for 3 weeks, then 20mg once daily (c) Prevention of recurrent DVT/PE after at least 6 months of treatment: 10 mg once daily or 20 mg once daily (d) Prevention of DVT/PE following knee replacement surgery: 10mg once daily for 14 days (e) Prevention of DVT/PE following hip replacement surgery: 10mg once daily for 35 days (f) Prevention of atherothrombosis following an acute coronary syndrome with elevated cardiac biomarkers (in combination with aspirin alone or aspirin and clopidogrel): 2.5mg twice daily (g) Prevention of atherothrombotic events in patients with coronary artery disease or symptomatic peripheral artery disease at high risk of ischaemic events (in combination with aspirin): 2.5mg twice daily RENAL IMPAIRMENT: in patients with creatinine clearance 15 - 49 ml/min, the following dosage recommendations apply: • For the prevention of stroke and systemic embolism in patients with non-valvular atrial fibrillation, the recommended dose is 15 mg once daily • For the treatment of DVT, treatment of PE 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 20 mg once daily. 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. After 6 months these patients will be reviewed to consider a dose of 10mg once daily. When the recommended dose is 10 mg once daily, no dose adjustment from the recommended dose is necessary. Rivaroxaban is contraindicated if CrCl <15mL/min.
7.	How to take: • Must be taken at the dose prescribed • Swallow the tablet whole with water • Aim to take at the same time each day • For doses of 15mg or 20mg, the dose must be immediately followed with a meal to improve absorption Are there any conditions which could affect your ability to take the tablet e.g. visual impairments, dexterity problems, swallowing difficulties, cognitive ability, literacy ability etc. Refer to haematologist if condition will effect ability to take medication or any safety concerns.
8	Missed doses: • If you remember within 12 hours of your regularly scheduled dose: take the tablet immediately and then take your usual dose at the regularly scheduled time. • If you remember more than 12 hours after your scheduled dose: miss that particular day's dose and take your usual dose the following day. **NEVER** double the prescribed dose in a single day. Never take larger or more frequent doses. For DVT/PE treatment between days 1 and 21: If a dose is missed during the 15 mg twice daily treatment phase, then take immediately to ensure intake of 30 mg rivaroxaban per day. In this case two 15 mg tablets may be taken at once. Then continue with the regular 15 mg twice daily intake as before on the following day.
9.	Adherence: Rivaroxaban has a shorter half-life compared to warfarin and efficacy is more likely to be affected if poorly adherent.
10.	Monitoring: Occasionally anticoagulant assays are needed to check levels in the context of weight extremes, renal failure or interacting medications and these should be guided by a haematologist.

	Routine monitoring of the FBC, U&E and LFT are required. Deterioration may require stopping/ a dose change/ switch to another anticoagulant. As per primary care prescriber guidelines:
	• Monitor FBC, U&E and LFT at least annually
	• Perform additional U&E checks every 6 months if:
	  • >75yrs
	  • Frail (defined as ≥3 of the following criteria: unintentional weight loss, self-reported exhaustion, weakness assessed by handgrip test, slow walking speed/gait apraxia, low physical activity)
	  • CrCl 30–60ml/min
	• Perform additional U&E checks every 3 months if:
	  • CrCl 15-29ml/min
	For patients being monitored by the GP refer to Primary Prescriber information in trust Shared Care Guidelines.
	Standard clotting tests do not predict the effect of direct anticoagulants

11.	Side effects of rivaroxaban (and what to do if experienced): Monitor at home: • Bruising (monitor size and growth) • Bleeding gums (ensure dental health is sufficient) • Nose bleeds (plug, pinch nose, use of cold pack, remain still and calm) Seek medical attention (GP/ local anticoagulant clinic): • Nose bleeds (lasting for >10 minutes, daily, difficult to control even with plugging) • Spontaneous bruising • Abnormally heavy periods or unexpected vaginal bleeding • Light red urine Seek medical attention (call NHS 111/999): • If involved in major trauma, suffer a significant injury to the head or are unable to stop bleeding (lasting >10 minutes) – seek immediate medical attention by calling an ambulance • Severe headaches • Red or black stools • Coughing up or vomiting blood or ground coffee like material • Bleeding that does not stop with appropriate first aid • Blood clots in urine • Severe bruising (spontaneous and unexplained) Any other side effects, discuss with GP or anticoagulant clinic. **For DVT/PE patients:** recurrence of thromboembolism: seek medical help if original symptoms recur. Risk is low if adherent. Also provide trust DVT and PE patient information leaflets for specific signs and symptoms.
12.	Potential for drug interactions: may be affected by some medicines/herbal preparations (see SPC for rivaroxaban) Therefore: • Patients should always let a doctor, dentist or pharmacist know that they are on rivaroxaban • Not to take aspirin, clopidogrel or any other anti-platelet therapy unless prescribed by doctor who is aware of rivaroxaban therapy, as increased risk of bleeding. Avoid NSAIDs such as ibuprofen, aspirin, diclofenac, naproxen etc (paracetamol or codeine are preferred) • Combinations of anticoagulants and antiplatelets should be reviewed with clinicians to determine whether the antiplatelet can be stopped. Consider prophylaxis against gastritis e.g. proton pump inhibitor

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13.	Alcohol intake: alcohol is not expected to affect rivaroxaban levels per se. However, excess alcohol consumption is generally not advised for anticoagulated patients, due to the risks of alcohol associated acute injuries (e.g. head injuries) and chronic liver disease (which may affect coagulation).
14.	Contraception, pregnancy, and hormone replacement therapy (if relevant): Women should not become pregnant nor breast feed whilst taking rivaroxaban. Reliable contraception is required. If a DVT/PE patient is currently taking HRT/OCP then discussions are required regarding stopping or appropriate choice (generally avoid oestrogen-containing preparations; progesterone only pill/implant/coil are preferred). **Ensure pregnancy has been excluded now**. For women taking rivaroxaban who may be pregnant, discuss alternatives with a Haematologist/obstetrician. If planning to become pregnant, the patient should plan alternatives with their GP and/or Haematologist.
15.	Hobbies and leisure activities: activities which may lead to injury, especially of the head (e.g. skiing, horse riding, boxing, martial arts, rugby or other contact sports) have an increased risk of bruising/bleeding.
16.	Can obtain further supplies of rivaroxaban from the hospital (or GP once care has been transferred). Get regular repeat prescriptions so as not to run out of tablets. Plan ahead at least 2 weeks particularly before going on holiday/bank holidays.
17.	They should inform healthcare professionals that they are taking rivaroxaban if: • admitted to hospital (to avoid duplication of therapy with standard DVT/PE thromboprophylaxis) • admitted for surgery (inform the admitting team and the pre-admission clinic) • they require an injection • they require dental procedures It may or may not be necessary to withhold your rivaroxaban, and the person doing the procedure should decide; if they are unsure they should contact the local anticoagulant clinic/Haematology for advice (contact details in patient information leaflet and PE/ DVT guidelines on WeShare). **Injections:** if deep/critical site e.g joint/eye/genitalia/spine it may be necessary to withhold rivaroxaban. For vaccinations it is sufficient to delay their dose for that day until after the injection and apply prolonged pressure to the site afterwards.
18.	For further advice/information contact local anticoagulation clinic/ GP/ Hospital pharmacy (Medicines Information department). In an emergency, contact NHS 111/A&E department.