

Edoxaban (Lixiana) counselling checklist

Patient Name: **Hospital Number:**

This patient has been counselled on the following areas of edoxaban therapy, by a pharmacist, doctor or anticoagulant practitioner, in accordance with the guidance overleaf.

	Counselling point	
1.	Indication for edoxaban	
2.	What an anticoagulant is and alternative anticoagulation options	
3.	Benefits and disadvantages of edoxaban compared to other anticoagulants	
4.	Expected duration of therapy - specify if known:	
5.	Basic mode of action	
6.	Dose	
7.	How to take: • Must be taken with water; can be taken with or without food • Aim to take 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? Contact doctor or healthcare team)	
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 edoxaban 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 edoxaban	
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 edoxaban 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.	<p>Edoxaban is licensed for:</p> <p>a) Prevention of stroke and systemic embolism in non-valvular AF, in patients with at least one risk factor, such as:</p> <ul style="list-style-type: none"> • previous stroke or transient ischaemic attack • congestive heart failure • age ≥ 75 years • diabetes mellitus • hypertension <p>b) Treatment of deep-vein thrombosis (DVT) or pulmonary embolism (PE)</p> <p>c) Prevention of recurrent DVT or PE</p>
2.	<p>Alternative anticoagulants: warfarin (and other vitamin k antagonists), low molecular weight heparin (LMWH), other direct oral anticoagulants (e.g. dabigatran, apixaban, rivaroxaban)</p> <ul style="list-style-type: none"> • For acute treatment and secondary prevention of symptomatic DVT/PE, edoxaban administered once daily after initial treatment with LMWH was non-inferior to warfarin. • For AF, edoxaban was shown to be non-inferior to warfarin for the prevention of stroke and systemic embolism, with consistently lower rates of major bleeding and haemorrhagic stroke events. Edoxaban also had lower rates of other bleeding events including fatal and intracranial bleeds. The single exception being gastrointestinal bleeding that occurred more frequently with high-dose edoxaban but less frequently with low-dose edoxaban than it did with warfarin.
3.	<p>Advantages (vs. warfarin): fixed dose, no routine coagulation monitoring, more stable anticoagulation control, lower risk of intracranial haemorrhage (AF patients). Edoxaban'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.</p> <p>Disadvantages (vs warfarin): unable to routinely monitor coagulation (measuring coagulation requires specialist tests that are not widely available), unlike warfarin no formal antidote, increased rates of gastrointestinal bleeding, limited long-term data.</p> <p>Advantage vs. rivaroxaban: does not need to be taken with food</p> <p>Advantage vs. dabigatran: smaller tablet, can be crushed or put in dosette box</p> <p>Disadvantage vs. dabigatran: no widely available direct antidote</p>
4.	<p>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. 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.</p>
5.	<p>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.</p>
6.	<p>Dose:</p> <p>(a) Prophylaxis of stroke and systemic embolism in non-valvular atrial fibrillation, in patients with at least one risk factor (such as congestive heart failure, hypertension, aged 75 years and over, diabetes mellitus, previous stroke or transient ischaemic attack)</p> <ul style="list-style-type: none"> • Body-weight ≤ 60 kg: 30 mg once daily. • Body-weight 61 kg and above: 60 mg once daily* <p>(a) Treatment of deep-vein thrombosis or pulmonary embolism and prevention of recurrent venous thromboembolism</p> <p>Initially at least 5 days of a parenteral anticoagulant then followed by;</p> <ul style="list-style-type: none"> • Body-weight ≤ 60 kg: 30 mg once daily • Body-weight 61 kg and above: 60 mg once daily * <p>Note: Edoxaban should not be administered simultaneously with the parenteral anticoagulant. *Max. dose of 30 mg once daily with strong p- glycoprotein inhibitors including ciclosporin,</p>

	dronedarone, erythromycin, or ketoconazole or in moderate to severe renal impairment (creatinine clearance (CrCL) 15 – 50 mL/min).
7.	<p>How to take:</p> <ul style="list-style-type: none"> • Must be taken at the dose prescribed • Swallow the tablet whole with water • Can be taken with or without food • Aim to take at the same time each day <p>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 hematologist if condition will effect ability to take medication or any safety concerns.</p>
8.	<p>Missed doses:</p> <ul style="list-style-type: none"> • 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. <p>NEVER double the prescribed dose in a single day. Never take larger or more frequent doses.</p>
9.	<p>Adherence:</p> <p>Edoxaban has a shorter half-life compared to warfarin and efficacy is more likely to be affected if poorly adherent.</p>
10.	<p>Monitoring:</p> <p>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:</p> <ul style="list-style-type: none"> • Monitor FBC, U&E and LFT at least annually • Perform additional U&E checks every 6 months if: <ul style="list-style-type: none"> • >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: <ul style="list-style-type: none"> • CrCl 15-29ml/min <p>For patients being monitored by the GP refer to Primary Prescriber information in trust Shared Care Guidelines.</p> <p>Standard clotting tests do not predict the effect of direct anticoagulants</p>
11.	<p>Side effects of edoxaban (and what to do if experienced):</p> <p>Monitor at home:</p> <ul style="list-style-type: none"> • 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) <p>Seek medical attention (GP/ local anticoagulant clinic):</p> <ul style="list-style-type: none"> • 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 <p>Seek medical attention (call NHS 111/ 999):</p> <ul style="list-style-type: none"> • 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

	<ul style="list-style-type: none"> • Blood clots in urine • Severe bruising (spontaneous and unexplained) <p>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.</p>
12.	<p>Potential for drug interactions: may be affected by some medicines/herbal preparations (see SPC for Edoxaban e.g. erythromycin, ciclosporin, dronedarone, ketoconazole) Therefore:</p> <ul style="list-style-type: none"> • Patients should always let their doctor, dentist or pharmacist know that they are on edoxaban • Not to take aspirin, clopidogrel or any other anti-platelet therapy unless prescribed by the doctor who is aware of edoxaban therapy, as increased risk of bleeding. Avoid NSAIDs such as ibuprofen, aspirin, diclofenac, naproxen etc (paracetamol or codeine is 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. • For patients that may require a course of erythromycin, this can increase exposure to edoxaban, therefore a dose adjustment is required on concurrent administration
13.	<p>Alcohol intake: alcohol is not expected to affect edoxaban 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).</p>
14.	<p>Contraception, pregnancy, and hormone replacement therapy (if relevant): Women should not become pregnant nor breast feed whilst taking edoxaban. 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 edoxaban who may be pregnant, discuss alternatives with the Haematologist /obstetrician. If planning to become pregnant, then patient should plan alternatives with their GP and/or Haematologist.</p>
15.	<p>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.</p>
16.	<p>Can obtain further supplies of edoxaban 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.</p>
17.	<p>They should inform healthcare professionals that they are taking edoxaban if:</p> <ul style="list-style-type: none"> • 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 <p>It may or may not be necessary to withhold your edoxaban, 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 edoxaban. For vaccinations it is sufficient to delay their dose for that day until after the injection and apply prolonged pressure to the site afterwards.</p>
18.	<p>For further advice/information contact local anticoagulation clinic/GP/Hospital pharmacy (Medicines Information department). In an emergency, contact NHS 111/A&E department.</p>