Barts Health NHS
NHS Trust

Dabigatran (Pradaxa) counselling

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

	Counselling point	
1.	Indication for dabigatran	
2.	What an anticoagulant is and alternative anticoagulation options	
3.	Benefits and disadvantages of dabigatran 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? 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 dabigatran 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 dabigatran	
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 dabigatran 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.**

Written by: Inderjit Singh Takher, October 2014, updated by Anika Pomie, January 2021
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General guidance on counselling points

Only provide information relevant to the patient

1.	Dabigatran is licensed for: (a) Prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation (NVAF), with one or more risk factors, such as: • prior stroke or transient ischemic attack (TIA) • age ≥ 75 years • heart failure (NYHA Class ≥ II) • diabetes mellitus • hypertension (b) Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE) (c) Prevention of recurrent DVT and PE in adults (d) Prevention of DVT/PE in adult patients undergoing elective hip/knee replacements
2.	Alternative anticoagulants: warfarin (and other oral vitamin K antagonists), low molecular weight heparin (LMWH), other direct oral anticoagulants (e.g. apixaban, rivaroxaban, edoxaban) • For AF, dabigatran was shown to be as effective as warfarin for the prevention of stroke and systemic embolism, with a lower risk of intracranial hemorrhage. There was a slightly higher incidence of dyspepsia and GI bleeds compared to warfarin. • For the treatment of acute DVT/PE: Dabigatran was shown to be as effective as warfarin.
3.	Advantages (vs. warfarin): fixed dose, no routine coagulation monitoring, more stable anticoagulation control, lower risk of intracranial haemorrhage (AF patients). Dabigatran's onset of actions 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 (measuring coagulation requires specialists tests that are not widely available), limited long-term data, short half-life (12 hours) means twice daily dosing regimen. Advantage vs. rivaroxaban: can be taken with or without food Disadvantage vs. rivaroxaban and edoxaban: twice daily dosing Disadvantage vs. edoxaban, apixaban, rivaroxaban: cannot be put in dossette box Advantage vs. edoxaban, apixaban, rivaroxaban: antidote widely available
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; 28-35 days. Prevention of DVT/PE in adult patients undergoing elective knee replacement; 10 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 (thrombin) 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 (NVAF), with one or more risk factors, such as prior stroke or transient ischaemic attack (TIA); age≥ 75 years; hypertension; diabetes mellitus; symptomatic heart failure (NYHA Class ≥ II):150mg twice daily (b) Treatment of DVT/PE and prevention of recurrent venous thromboembolism: initially at least 5 days of a parenteral anticoagulant followed by 150mg twice daily

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	(c) Prevention of DVT/PE following knee replacement surgery: 110mg 1-4 hours post-op, then 220mg once daily for 10 days (d) Prophylaxis of DVT/PE following hip replacement surgery: 110mg 1-4 hours post-op, then 220mg once daily for 28-35 days RENAL IMPAIRMENT: For AF, treatment and prevention of recurrent DVT/PE; dose reduction to 110mg twice daily if aged 80 years or over or drug interactions (see SPC for dabigatran for more details). Consider dose reduction in the following groups based on an individual assessment of the thromboembolic risk and the risk of bleeding; patient aged 75-80years, CrCl 30-50mL/min, gastritis, esophagitis, gastroesophageal reflux or other patients at increased risk of bleeding. For prevention of DVT/PE in orthopedic surgery; dose reduction recommended to 75mg 1-4 hours post op, then 150mg once daily if CrCl 30-50mL/min, aged 75 year or above or drug interactions (see SPC for dabigatran for more details). Dabigatran is contraindicated if CrCl <30mL/min.
7.	How to take: • Must be taken at the dose prescribed • Swallow the tablet whole with water; do not open contents of capsules and swallow as this could lead to increase bioavailability thus increasing bleeding risk • Can be taken with or without food • Aim to take at the same time each day • Dabigatran needs to be kept in its original packaging (i.e. not to transfer to a compliance aid, dossette box, or bottle). 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: Twice daily regime: • If you remember within 6 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 6 hours after your scheduled dose: miss that particular dose and take your usual next dose when it is due. Once daily regime: • 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 dose and take your usual next dose when it is due. **NEVER** double the prescribed dose in a single day. Never take larger or more frequent doses.
9.	Adherence: Dabigatran 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
	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 dabigatran (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 dabigatran) Therefore: • Patients should always let a doctor, dentist or pharmacist know that they are on dabigatran • Not to take aspirin, clopidogrel or any other anti-platelet therapy unless prescribed by doctor who is aware of Dabigatran 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
13.	Alcohol intake: alcohol is not expected to affect dabigatran 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 dabigatran. 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 dabigatran 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 dabigatran 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 dabigatran 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 dabigatran, 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 dabigatran. 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.	Further advice/information from local anticoagulation clinic/GP/Hospital pharmacy (Medicines Information department). In an emergency, contact NHS 111/A&E department.