



Direct Oral Anticoagulant Therapy Record

Patient:

.....



Inside Front Cover

FOREWORD

The landscape of oral anticoagulation therapy has been rapidly advancing and the range of indications for which these medications are approved are also expanding.

Patient adherence to any medication regimen is fundamental to favorable patient outcomes and central to adherence is the quality of education about their condition and how it is treated. The aim of this information booklet is to help patients understand their illness and weigh the risks and benefits of treatment.

The Ireland East Hospital Group is committed to bringing patients up-to-date and simplified information to help them manage their illness with good quality of life. This booklet is the result of considerable collective effort of senior clinicians and pharmacists and with its publication we are establishing standard treatment protocols for providing the highest quality and most cost-effective health care.

I would like to express my gratitude to Ms Deirdre Lenehan, MMUH Drug Safety Facilitator, the MMUH Drug Safety Committee and all those involved in drafting this invaluable booklet which will greatly benefit our patients.

*Professor Mary Day,
Group Chief Executive,
Ireland East Hospital Group (IEHG)*

IEHG have produced and maintain this Therapy Record solely for the benefit of IEHG patients. Every effort is made to ensure that the information contained therein is up to date and accurate. The Record is the property of IEHG and the information contained therein cannot be altered or copied without its consent.

IEHG accepts no responsibility for the user of the Therapy Record by persons who are not patients of IEHG.

Dear Patient,

Always carry this booklet with you.

Show it to all doctors, dentists or pharmacists that you attend.

Show it to everyone giving you treatment that can cause bleeding, such as surgery or tooth extraction.

Always keep your anticoagulant medication out of the sight and reach of children.

INDEX

Section 1. Page 4 Direct Oral Anticoagulant Therapy Record

(For Doctor & Patient) To be completed by the doctor initiating anticoagulant therapy in consultation with the patient.

Section 2. Page 7 Information for the patient

(For Patient) What you should know about this medication.

Section 3. Page 20 Practical guide for the doctor starting or managing the patient on a Direct Oral Anticoagulant.

(For Doctor)

Section 4. Page 26 Action Plan to be completed by the doctor managing the patient on a Direct Oral Anticoagulant.

(For Doctor)

Section 5. Page 30 Direct Oral Anticoagulant Dosing Guidelines.

(For Doctor)

Section 2 of this booklet, Information for the patient, has been approved by the National Adult Literacy Agency and awarded the Plain English Mark.



Direct Oral Anticoagulant Therapy Record

To be completed by the doctor starting a patient on Direct Oral Anticoagulant therapy. The doctor should complete the form **in consultation with the patient.**

Name:

Address:

.....

.....

Telephone No:

Date of Birth:_....._.....

Medical Record Number:

Please Tick Reason for treatment:

- Stroke Prevention
- Treatment of blood clot
- Prevention of blood clot

Your Direct Oral Anticoagulant treatment:

Drug: Dose:
(include initial dose and subsequent maintenance dose if relevant)

Refer to **Section 4** for most recent dose.

Reason for adjusted dose (if relevant):

.....

Date of starting treatment:_....._.....

Serum creatinine when starting treatment: micromoles / L

Creatinine clearance when starting treatment: ml / min

Weight when starting treatment: kg

Expected length of treatment

Next out-patient review (if appropriate) months

Name of Physician (and specialty) that started treatment:

.....

General Practitioner (GP):

.....

GP Address:

.....

.....

GP telephone number:

Additional information / Management plan:

The Community Pharmacy may ask the patient for the PCRS Approval Reference before dispensing this medication for the patient. Please write PCRS Approval Reference below:

PCRS Approval Reference:

Information for patients

This section aims to tell you what you need to know about your anticoagulant medication, and to answer your questions about it.

1. What is an anticoagulant?

An anticoagulant, or Direct Oral Anticoagulant (DOAC), or New Oral Anticoagulant (NOAC), is sometimes referred to as a 'blood thinner'. If your blood is thinner, it will take longer to clot, which helps to prevent harmful clots forming in your blood vessels.

The information in this booklet does **not** apply to Warfarin – a different, older oral anticoagulant.

2. Why am I taking this medication?

You are taking this medication to thin your blood.

You are either taking it to:

- Prevent a stroke,
- To treat a blood clot, or
- Prevent a blood clot from forming.

All of these reasons are explained in more detail below, and the specific reason why you are taking the medication is ticked on page 4 of this booklet.

Stroke prevention

If you have a form of irregular heart rhythm (also called non-valvular atrial fibrillation) **or** if your doctor suspects that a blood clot came from your heart to your brain and may have caused a stroke or mini-stroke (transient ischaemic attack or TIA), this drug will prevent blood clots forming in your brain or other blood vessels in your body.

Treatment of blood clot

If you have been diagnosed with a blood clot (for example, in your lungs or your legs), this medication will treat that.

Prevention of blood clot

If you are at risk of developing a blood clot (for example, in your lungs or legs), this medication will help to prevent that.

3. How do I take this medication?

This medication is oral – in other words, it is a pill that you swallow. At the moment, your doctor can prescribe four different types of Direct Oral Anticoagulants. The type they prescribe will depend on your needs.

No matter which one you are taking, there are a few key points to remember:

- It is very important that you take this medication **every day**. Forgetting doses may make you more likely to develop a blood clot, which could cause a stroke, lung clot or leg clot.
 - It is important to take your medication **at the same time** every day.
 - Swallow your medication with a drink of water.
- Below, we describe how to take each of the medications in more detail. We also explain what you should do if you forget to take a dose.

The medication you are taking is listed on [page 4](#).

Apixaban (Eliquis®): Twice a day (12 hours apart)
Apixaban can be taken with or without food.

If you forget to take it:

- Take the forgotten dose only if you remember **within 6 hours** of the time you normally take it, and then continue as normal.
- **Do not take** the forgotten dose if you remember **more than 6 hours** after the time you normally take it. Take the next dose when it is due. Continue at the normal times the next day. Make a note of the date, and remember to tell your doctor about any forgotten doses.
- **Never take a double dose** (two doses at the same time) to make up a forgotten dose.

Dabigatran (Pradaxa®): Twice a day (12 hours apart)

Dabigatran can be taken with or without food.

If you forget to take it:

- Take the forgotten dose only if you remember **within 6 hours** of the time you normally take it, and then continue as normal.
- **Do not take** the forgotten dose if you remember **more than 6 hours** after the time you normally take it. Take the next dose when it is due. Continue at the normal times the next day. Make a note of the date, and remember to tell your doctor about any forgotten doses
- **Never take a double dose** (two doses at the same time) to make up a forgotten dose.

Edoxaban (Lixiana®): Once a day

Edoxaban can be taken with or without food

If you forget to take it:

- Take the forgotten dose immediately – as long as it's the same day the dose was due. Continue at the normal time the next day. Make a note of the date, and remember to tell your doctor about any forgotten doses.
- **Never take a double dose** (two doses at the same time) to make up a forgotten dose.

**Rivaroxaban (Xarelto®): Once a day or twice a day
Must be taken with food.**

**If your dose is once
a day:**

Take it once a day to prevent a stroke or from Day 22 onwards to treat or prevent a blood clot. Remember, Rivaroxaban must be taken **with food**.

If you forget to take it, and it's still the same day the dose was due, take the forgotten dose immediately and continue at the normal time the next day.

Never take a double dose (two doses at the same time)

**If your dose is twice
a day:**

Take it twice a day for the first 21 days to treat or prevent a blood clot.

After that (from Day 22), take it once a day (see the instructions in the grey column to your left). Remember, Rivaroxaban must be taken **with food**. If you forget to take it, and it's still the same day the dose was due, take the forgotten dose immediately.

This may **even mean taking two tablets together**.

to make up a forgotten dose.

Make a note of the date, and remember to tell your doctor about any forgotten doses.

This is only allowed if you are taking Rivaroxaban **twice a day**. Continue to take doses at the normal times the next day.

Make a note of the date, and remember to tell your doctor about any forgotten doses.

4. Can I take other medications with this Direct Oral Anticoagulant?

It depends. Some medications – for example, ‘over the counter’ (OTC) medications like Ibuprofen or prescription medications like Diclofenac – can affect how your anticoagulant treatment works. **Always tell your doctor, dentist or anyone else treating you** that you are taking an anticoagulant medication.

Before starting any new medication, including those prescribed by a doctor, **ask your pharmacist or your usual doctor for advice.**

5. How long will I be taking this medication for?

Your doctor will tell you how long you will need to take this medication for. See 'Expected length of treatment' on page 5 of this booklet. If you are not sure about this, ask your doctor.

6. What about side effects?

The main potential side effect of taking a blood thinner is that you are at greater risk of bleeding. Bleeding is a potential side effect of any blood-thinning medication and it can be serious. Tell your doctor straight away if you notice bleeding, especially if you experience any of the following:

- Unexpected or uncontrollable bleeding
- Coughing up or vomiting blood

- Black stools or blood in your stools
- A fall or injury to your head or face
- Blood in your urine
- Unexplained or severe bruising
- A severe headache that will not go away
- Paleness, dizziness or weakness

If you feel dizzy or have headaches, do not drive or use machinery. Other side effects include stomach upset and stomach pain.

Contact your doctor if you develop any side effects.

7. Is there a drug to reverse the effects of this medication?

Some of the Direct Oral Anticoagulants can be reversed. If you would like more information about this, you should discuss it with your doctor.

8. Will I need to have lots of blood tests?

Not really. Your GP or hospital doctor will organise blood tests when you need them, which could be every 3 months or every 6 months or maybe even just once a year. These tests are needed to make sure you are on the correct dose of medication, and to check your kidney function.

You can keep track of your blood tests, medication, review appointments, and so on by getting your GP or hospital doctor to complete **Section 4** of this booklet

(the Action Plan) every time you discuss your treatment with them.

9. Is there anything else I need to know about this medication?

- You should always make sure you have about one week's extra supply of this medication as you must never run out of it.

- Remember that your risk of bleeding is higher, so please take this into account before taking part in activities with a high risk of injury – for example, rugby, skiing, hurling, cycling and so on.
- If you become pregnant, or you plan to become pregnant while taking this medication, tell your doctor straight away because the effects of this medication during pregnancy are not known and you may need to change to a different medication.
- If you are scheduled for surgery of any description (including dental work), please tell your doctor or dentist that you are on this medication. You might need to stop taking it for a short time to reduce the risk of bleeding.

Practical guide for the doctor starting or managing the patient on a Direct Oral Anticoagulant (DOAC)

For all patients being started on a DOAC (as a first-line anticoagulant or second-line anticoagulant following Warfarin discontinuation), it is your responsibility as the prescribing clinician to ensure that a **structured care pathway** has been put in place to manage the patient's DOAC.

If a patient continues to attend the clinic of the consultant that originally prescribed the DOAC, that consultant must provide the **structured care pathway**.

If a patient is discharged from that consultant's clinic, it is the responsibility of the patient's GP to provide the on-going **structured care pathway**. It is important to discuss this with the GP.

If changing a patient from Warfarin to a DOAC, please complete the additional steps in the pathway on pages 23 & 24.

Structured care pathway:

Assess the patient's suitability for a DOAC

1. Order the following baseline investigations – FBC, liver and renal profile.
2. Review the patient's medications to determine if they are taking any interacting medications. If the patient is on an interacting medication, it may mean the DOAC is contraindicated / DOAC dose must be altered / additional caution or monitoring is needed.
3. Check the Summary of Product Characteristics on www.hpra.ie or local hospital / ICGP guidance to determine a suitable DOAC drug, dose and frequency based on the patient's baseline investigations and concomitant medications.

You can find a quick reference guide on Direct Oral Anticoagulant Dosing Guidelines in **Section 5** of this booklet.

4. Avoid therapeutic duplication

- A DOAC should **not** be used at the same time as a parenteral anticoagulant. 'Bridging' is **never** required with DOACs
- For treatment of DVT/ PE:
 - Dabigatran / Edoxaban should be initiated after at least 5 days treatment with a parenteral anticoagulant. **Stop** the parenteral anticoagulant and then **start** Dabigatran or Edoxaban.
 - Apixaban / Rivaroxaban do not require this 5 day 'lead-in' with a parenteral anticoagulant.

5. Obtain a **PCRS Approval Reference** for the DOAC on www.sspcrs.ie/portal/individualReimbursement/pub (case sensitive). Document this reference on page 6 of this booklet.

Ensure adequate clinical monitoring of a DOAC

A clinical monitoring schedule must be planned with the patient. The following should be reviewed regularly by the patient's hospital doctor or GP:

- Dose - A quick reference guide on Direct Oral Anticoagulant Dosing Guidelines is provided in **Section 5** of this booklet.
- Bloods - FBC, liver profile, renal profile
- Adherence with DOAC therapy
- Concomitant medications
- Any thromboembolic events / bleeding events / side effects

- Renal function
 - Laboratory monitoring of renal function should be planned at least yearly, but possibly more often in some high risk patient categories, for example:
 - The elderly
 - Patients with impaired renal function at baseline
 - Patients with relevant concomitant medications
 - Patients with diseases potentially affecting renal function
 - Renal function should also be immediately assessed in the setting of clinical conditions that could cause renal function to deteriorate, for example:
 - Dehydration
 - Acute medical diseases (including congestive heart failure, infections, acute inflammatory disorders)
 - Need for hospitalisation
 - **The following may be used as a guide for monitoring renal function in patients taking DOACs:**

Renal Function	Monitor
CKD stage I – II (CrCl \geq 60 ml / min)	Yearly
CKD stage III (CrCl 30 – 59 ml / min)	6 Monthly
CKD stage IV (CrCl \leq 29 ml / min)	3 Monthly

- **Section 5** in this booklet includes dosing guidelines for patients with renal impairment. These guidelines are based on creatinine clearance (CrCl)(Cockroft & Gault calculation) as per SmPC recommendations, but for most patients of average build and height, eGFR (MDRD calculation) may be used. CrCl should be used to adjust drug dosages in patients at extremes of body weight (BMI $<$ 18.5 kg / m² or $>$ 30 kg / m²).

Please note: If a DOAC dose has been reduced as a result of an acute change in medical condition, it may need to be increased again once renal function has recovered.

Section 4 provides an Action Plan to be completed by the patient's GP or hospital doctor at regular intervals. The frequency of these intervals will depend on the patient's clinical condition and should be decided on a case-by-case basis. If necessary, GPs should contact the clinician that started the patient on a Direct Oral Anticoagulant to discuss this or any other aspect of the patient's anticoagulant therapy further if necessary.

Involve the patient in their DOAC therapy

1. Give the patient this booklet and complete **Section 1** with them.
2. Advise the patient to make sure their bloods and medications have been reviewed before starting their DOAC.
3. Use **Section 2** of this booklet to educate the patient on their DOAC.

Document the plan for DOAC initiation:

1. Clearly document all aspects of this **structured care pathway** in the medical records.
2. Communicate this plan with the patient's GP by including it in the patient's discharge information.

Additional steps for changing patients from Warfarin to a DOAC:

If a DOAC is deemed more suitable for a patient who is on Warfarin therapy then the following steps must be completed **in addition** to implementation of the **structured care pathway** above:

The patient

1. Advise the patient to make an appointment (a new appointment if they are not due back to the Warfarin Clinic in the coming weeks) with the Warfarin Clinic and to stop taking their Warfarin the day before they go to their appointment. Also advise the patient to inform the clinic that they are starting a DOAC.
2. Give the patient a prescription for the DOAC and advise them to fill the prescription as soon as possible to ensure they will have the DOAC with them when they are ready to start it. If there is a delay in filling the prescription or making the clinic appointment, the patient must be advised to continue taking their warfarin.
3. **NB:** Educate the patient about the fact that the INR must be < 2 before starting a DOAC. Patients may have been familiar with taking injections (low molecular weight heparin) when their INR was low. Explain to the patient that they will no longer need injections once the DOAC is started.

The Warfarin Clinic

1. Written information about the patient's changeover to a DOAC must be provided to the Clinic. Please provide specific instructions in the box **below** which the patient can show to the nurses in the Warfarin Clinic.
2. Document the plan for changeover to a DOAC clearly in the medical notes including all aspects of the **structured care pathway** outlined above. The Warfarin Clinic nurses may need to review the medical notes or contact the team for further information, to safely change the patient over to a DOAC.

Management plan for changing patient from Warfarin to a DOAC:

The information provided for prescribers in this booklet is not exhaustive. For further clinical information, for example, on the use of antiplatelet therapies with DOACs, consult the product literature on www.hpra.ie or contact a hospital-based specialist / the National Medicines Information Service (www.nmic.ie) for advice.

Date	Age	Weight (kg)	Serum Creatinine (micromoles / L)	CrCl ml /min	Current Direct Oral Anticoagulant, dose and frequency
_ _					
Any actions required? Yes <input type="checkbox"/> No <input type="checkbox"/> If yes, please detail:			Does Direct Oral Anticoagulant dose need to change? Yes <input type="checkbox"/> No <input type="checkbox"/> If yes, please detail new dose:		
Any compliance issues?	Any change in other medications?	Any atherothrombotic/bleeding /adverse events?		Next Review date:	
				_ _	

Date	Age	Weight (kg)	Serum Creatinine (micromoles / L)	CrCl ml /min	Current Direct Oral Anticoagulant, dose and frequency
_ _					
Any actions required? Yes <input type="checkbox"/> No <input type="checkbox"/> If yes, please detail:			Does Direct Oral Anticoagulant dose need to change? Yes <input type="checkbox"/> No <input type="checkbox"/> If yes, please detail new dose:		
Any compliance issues?	Any change in other medications?	Any atherothrombotic/bleeding /adverse events?		Next Review date:	
				_ _	

Date	Age	Weight (kg)	Serum Creatinine (micromoles / L)	CrCl ml /min	Current Direct Oral Anticoagulant, dose and frequency
_ _					
Any actions required? Yes <input type="checkbox"/> No <input type="checkbox"/> If yes, please detail:			Does Direct Oral Anticoagulant dose need to change? Yes <input type="checkbox"/> No <input type="checkbox"/> If yes, please detail new dose:		
Any compliance issues?	Any change in other medications?	Any atherothrombotic/bleeding /adverse events?		Next Review date:	
				_ _	

Date	Age	Weight (kg)	Serum Creatinine (micromoles / L)	CrCl ml /min	Current Direct Oral Anticoagulant, dose and frequency
_ _					
Any actions required? Yes <input type="checkbox"/> No <input type="checkbox"/> If yes, please detail:			Does Direct Oral Anticoagulant dose need to change? Yes <input type="checkbox"/> No <input type="checkbox"/> If yes, please detail new dose:		
Any compliance issues?	Any change in other medications?	Any atherothrombotic/bleeding /adverse events?		Next Review date:	
				_ _	

Date	Age	Weight (kg)	Serum Creatinine (micromoles / L)	CrCl ml /min	Current Direct Oral Anticoagulant, dose and frequency
_ _					
Any actions required? Yes <input type="checkbox"/> No <input type="checkbox"/> If yes, please detail:			Does Direct Oral Anticoagulant dose need to change? Yes <input type="checkbox"/> No <input type="checkbox"/> If yes, please detail new dose:		
Any compliance issues?	Any change in other medications?	Any atherothrombotic/bleeding /adverse events?		Next Review date:	
				_ _	

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Any compliance issues?	Any change in other medications?	Any atherothrombotic/bleeding /adverse events?		Next Review date:	
				_ _	

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Any actions required? Yes <input type="checkbox"/> No <input type="checkbox"/> If yes, please detail:			Does Direct Oral Anticoagulant dose need to change? Yes <input type="checkbox"/> No <input type="checkbox"/> If yes, please detail new dose:		
Any compliance issues?	Any change in other medications?	Any atherothrombotic/bleeding /adverse events?	Next Review date:		
			_ _		

Date	Age	Weight (kg)	Serum Creatinine (micromoles / L)	CrCl ml /min	Current Direct Oral Anticoagulant, dose and frequency
_ _					
Any actions required? Yes <input type="checkbox"/> No <input type="checkbox"/> If yes, please detail:			Does Direct Oral Anticoagulant dose need to change? Yes <input type="checkbox"/> No <input type="checkbox"/> If yes, please detail new dose:		
Any compliance issues?	Any change in other medications?	Any atherothrombotic/bleeding /adverse events?	Next Review date:		
			_ _		

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_ _					
Any actions required? Yes <input type="checkbox"/> No <input type="checkbox"/> If yes, please detail:			Does Direct Oral Anticoagulant dose need to change? Yes <input type="checkbox"/> No <input type="checkbox"/> If yes, please detail new dose:		
Any compliance issues?	Any change in other medications?	Any atherothrombotic/bleeding /adverse events?	Next Review date:		
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Any compliance issues?	Any change in other medications?	Any atherothrombotic/bleeding /adverse events?	Next Review date:		
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Any compliance issues?	Any change in other medications?	Any atherothrombotic/bleeding /adverse events?	Next Review date:		
			_ _		

Direct Oral Anticoagulant Dosing Guidelines ^{1,2,3,4} - see page 32

Renal dosing guidelines in this booklet are based on CrCl (Cockcroft & Gault calculation) as per SmPC recommendations, but for most patients of average build and height, eGFR (MDRD calculation) may be used. CrCl should be used to adjust drug doses in patients at extremes of body weight (BMI < 18.5 kg / m² or > 30 kg / m²). For further prescribing information, (e.g. drug interactions) please refer to SmPCs on www.hpra.ie.

Apixaban Indication	Dose	Renal impairment
To prevent stroke	5 mg BD	CrCl ≥ 30 ml / min: Usual dose (see across) CrCl 15 – 29 ml / min: 2.5 mg BD CrCl < 15 ml / min: Avoid.
	2.5 mg BD if at least two of the following: • Weight ≤ 60 kg, • Age ≥ 80 years • Serum creatinine ≥ 133 micromoles / L	
To treat leg / lung clots	10 mg BD for 7 days, then 5 mg BD	Use with caution in CrCl 15 - 29 ml / min
To prevent recurrent leg / lung clots	2.5 mg BD	

Dabigatran Indication	Dose	Renal impairment
To prevent stroke To treat leg / lung clots [^] To prevent recurrent leg / lung clots	150 mg BD	CrCl > 50 ml / min: Usual dose (see across) CrCl 30 – 50 ml / min: 150 mg BD or 110 mg BD depending on bleeding risk vs thromboembolic risk. CrCl < 30 ml / min: Avoid.
	110 mg BD* if ≥ 80 years or concomitant Verapamil. Also consider 110 mg BD* if high bleeding risk, e.g. CrCl 30 – 50 ml / min, age 75 – 80 years, gastritis, oesophagitis or gastroesophageal reflux.	

[^] For treatment of DVT / PE, it is recommended to commence Dabigatran following at least 5 days treatment with a parenteral anticoagulant.

* For DVT / PE, the recommendation for the use of 110 mg BD is based on pharmacokinetic analyses and has not been studied in this clinical setting.

Edoxaban Indication	Dose	Renal impairment
To prevent stroke To treat leg / lung clots [^] To prevent recurrent leg / lung clots.	60 mg once daily	CrCl > 50 ml / min: Usual dose (see across) CrCl 15 – 50 ml / min: 30 mg once daily CrCl < 15 ml / min: Avoid
	30 mg once daily if one or more of the following: • Weight ≤ 60 kg • CrCl 15 – 50 ml / min • Co-administration with P-GP inhibitors, e.g. Cyclosporin, Dronedaron, Erythromycin, Ketoconazole	

[^] For treatment of DVT / PE, it is recommended to commence Edoxaban following at least 5 days treatment with a parenteral anticoagulant.

Rivaroxaban Indication	Dose	Renal impairment
To prevent stroke	20 mg once daily	CrCl ≥ 50 ml / min: Usual dose (see across) CrCl 15 – 49 ml / min: 15 mg once daily; use with caution CrCl < 15 ml / min: Avoid
To treat and prevent leg / lung clots	Day 1 – 21: 15 mg BD for 21 days Day 22 onwards: 20 mg once daily. Consider dose reduction to 15 mg once daily if bleeding risk outweighs risk for recurrent DVT / PE ^Ω .	CrCl ≥ 15 ml / min: Usual dose (see across) ∞ CrCl < 15 ml / min: Avoid

^Ω Recommendation for the use of 15 mg daily is based on pharmacokinetic modelling and has not been studied in this clinical setting.

∞ Due to increased bleeding risk, the following drugs are cautioned with Rivaroxaban if CrCl 15 – 50 ml / min: Verapamil, Diltiazem and Amiodarone.

¹ Pradaxa® (Dabigatran) 150 mg hard capsules SmPC. Last updated on www.medicines.ie 21/06/2017. Accessed 05/07/2017

² Xarelto® (Rivaroxaban) 20mg film-coated tablets SmPC. Last updated on www.medicines.ie 18/05/2017. Accessed 05/07/2017

³ Eliquis® (Apixaban) 5mg film coated tablets SmPC. Last updated on www.medicines.ie 27/02/2017. Accessed 05/07/2017

⁴ Lixiana® (Edoxaban) 60 mg film-coated tablets SmPC. Last updated on www.medicines.ie 25/08/2016. Accessed on 05/07/2017 .

Inside Back Cover



Section 2 of this booklet, Information for the patient, has been approved by the National Adult Literacy Agency and awarded the Plain English Mark.



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