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Boehringer Ingelheim

When a full dose NOAC isn't the answer for stroke prevention in NVAF, consider Pradaxa 110

R110

Pradaxa® 110 dabigatran etexilate

Low dose, strong data

Pradaxa® 110 allows for **clinician-led prescribing based on your patient's bleeding risk**

Pradaxa® 110 has a **high standard of safety and efficacy evidence**

A low-dose NOAC with a **specific reversal agent**

Pradaxa® 110 allows for clinician-led prescribing based on your patient's bleeding risk

Pradaxa® 110 is the **only** low-dose non-vitamin K antagonist oral anticoagulant (NOAC) for stroke prevention in adult patients with NVAF that can be prescribed based on your own assessment of your patient's bleeding risk.*[1]

Pradaxa® 110 provides flexibility to choose the right evidence-based dose, giving you the confidence to dose reduce in your high bleed risk NVAF patients.

Renal function should be assessed by calculating the creatinine clearance (CrCL) prior to initiation of treatment. Pradaxa® is contraindicated in patients with severe renal impairment (i.e. CrCL <30mL/min).[1] Prior to prescribing Pradaxa® please ensure that you have assessed the patient's risk of stroke, risk of bleeding and their renal function. These will help you determine the patient's suitability for Pradaxa® and the appropriate dose for them.

Recommendations vary for the use of low-dose NOACs for stroke prevention in adults with NVAF who have one or more risk factors for stroke

Pradaxa® 110mg b.d.[1]	Apixaban 2.5mg b.d.[2]	Rivaroxaban 15mg o.d.[3]	Edoxaban 30mg o.d.[4]
May be prescribed in patients at increased risk of bleeding* Patients who are ≥80 years old, or are receiving concomitant verapamil should be dose reduced	Patient **must have** at least two of the following factors: • Age ≥80 years • Body weight ≤60kg • Serum creatinine ≥1.5mg/dL (133 micromol/L) Or the following factor: • Creatinine clearance 15–29mL/min†	Patient **must have** at least one of the following factors: • Moderate renal impairment: creatinine clearance 20–49mL/min • Severe renal impairment: creatinine clearance 15–29mL/min	Patient **must have** at least one of the following factors: • Creatinine clearance 15–50mL/min • Body weight ≤60kg • Receiving concomitant P-glycoprotein inhibitors (ciclosporin, dronedarone, erythromycin, ketoconazole)

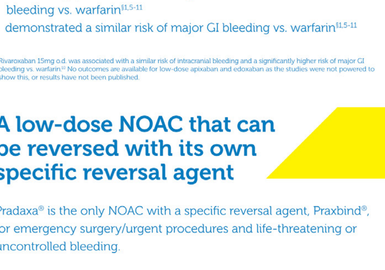
*Dose reduction should be considered based on your assessment of the patient's bleeding risk. Examples of increased bleeding risk may include: patients between 75–80 years; with moderate renal impairment (creatinine clearance 30–50mL/min); with gastritis, oesophagitis or gastroesophageal reflux. For further details of factors which may increase the bleeding risk please refer to the Summary of Product Characteristics. Pradaxa® is contraindicated in patients with severe renal impairment (creatinine clearance <30ml/min).

† Creatinine clearance should be calculated using the Cockcroft-Gault formula to determine dosage adjustments for NOACs.

Pradaxa® 110 has a high standard of safety and efficacy evidence

With a robust safety profile supported by over 6,000 patients and established efficacy results, Pradaxa® 110 is a low-dose NOAC with strong data.[1,5-7]

Percentage of patients studied on an approved low-dose NOAC for stroke prevention in NVAF in clinical trials:[1,5-11]



†These patient populations received low-dose treatment following dose reductions based on specific patient criteria.

As the only NOAC to have a similar number of patients with NVAF studied in both licensed dosing regimens, and with over 6,000 patients-worth of data, Pradaxa® 110 has a well-established and proven efficacy and safety profile.[1,5-7]

In adult patients with NVAF and at risk of stroke or systemic embolism, Pradaxa® 110mg was non-inferior to warfarin for the prevention of stroke and systemic embolism (primary outcome), and significantly reduced the risk of major bleeding (primary safety outcome), intracranial haemorrhage, and total bleeding vs. warfarin.[1,5-7]

Pradaxa® 110 is the **only** low-dose NOAC for stroke prevention in NVAF that:

- is **clinically proven** to show a significant reduction in intracranial bleeding vs. warfarin[11,5-11]
- demonstrated a similar risk of major GI bleeding vs. warfarin[11,5-11]

‡ Rivaroxaban 15mg o.d. was associated with a similar risk of intracranial bleeding and a significantly higher risk of major GI bleeding vs. warfarin.[10] No outcomes are available for low-dose apixaban and edoxaban as the studies were not powered to show this, or results have not been published.

A low-dose NOAC that can be reversed with its own specific reversal agent

Pradaxa® is the only NOAC with a specific reversal agent, Praxbind®, for emergency surgery/urgent procedures and life-threatening or uncontrolled bleeding.

For your patients treated with Pradaxa® 110, Praxbind® offers reassurance of immediate, complete and sustained reversal of the anticoagulant effects of Pradaxa® when required in emergency situations.[12-14]

As the specific reversal agent for Pradaxa, Praxbind® is on the National Antidote List and must be available within 1 hour to all Emergency Departments (i.e. within the hospital)[15]

Click here for more information about Pradaxa® 110 and Praxbind®

Pradaxa® (150mg and 110mg hard capsules) is indicated for the prevention of stroke and systemic embolism in adult patients with non-valvular AF, 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.[1,*]

Praxbind® (idarucizumab) is a specific reversal agent for dabigatran and is indicated in adult patients treated with Pradaxa® (dabigatran etexilate) when rapid reversal of its anticoagulant effects is required:

- For emergency surgery/urgent procedures
- In life-threatening or uncontrolled bleeding[12]

For more information, or to access the current prescriber guide and summary of product characteristics, please visit www.medicines.org.uk/emc

References:

1. Pradaxa® 110mg Summary of Product Characteristics.
2. Apixaban Summary of Product Characteristics.
3. Rivaroxaban Summary of Product Characteristics.
4. Edoxaban Summary of Product Characteristics.
5. Connolly SJ, et al. N Engl J Med. 2009;361:1139–51.
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8. Giugliano RP, et al. N Engl J Med. 2013;369:2093–2104.
9. Patel MR, et al. N Engl J Med. 2011;365(10):883–91.
10. Fox KAA., et al. Eur Heart J. 2011;32:2387–94.
11. Granger CB., et al. N Engl J Med. 2011;365:981–92.
12. Praxbind® Summary of Product Characteristics.
13. Pollack CV., et al. N Engl J Med. 2017;377(5):431-11.
14. Schiele F, et al. Blood. 2015;122(18):3554–62.
15. Royal College of Emergency Medicine and National Poisons Information Service Guideline on Antidote Availability for Emergency Departments. January 2017.
16. Pradaxa® 150mg Summary of Product Characteristics.

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Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Boehringer Ingelheim Drug Safety on 0800 328 1627 (freephone).

Pradaxa® dabigatran etexilate | Praxbind® idarucizumab

Anticoagulate With Confidence

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