The only NOAC with a SPECIFIC REVERSAL AGENT

Pradaxa is the only NOAC with a specific reversal agent funded and available throughout New Zealand[6]

Accidents do happen

1.5% of patients in RE-LY required an emergency procedure/yr[3-5]

References:
1.Pradaxa Data Sheet June 2019. **2.**Hijazi Z et al. Circulation 2014;129:961-970. **3.**Connolly SJ et al. N Engl J Med 2009;361:1139-1151. **4.**Connolly SJ et al. N Engl J Med 2010;363:1875- 1876. **5.**Connolly SJ, et al. N Engl J Med 2014; 371(15): 1464-5. **6.**Praxbind Data Sheet June 2019. **7.**Böhm M et al. JACC 2015;65(23):2481-2493

PRADAXA® (dabigatran etexilate) 75 mg, 110 mg and 150 mg capsules. Before prescribing, please review the full Data Sheet which is available on request from Boehringer Ingelheim or from http://www.medsafe.govt.nz/profs/datasheet/dsform.asp

INDICATIONS: *SPAF:* Prevention of stroke, systemic embolism and reduction of vascular mortality in patients with non-valvular atrial fibrillation with one or more of the following risk factors: previous stroke, transient ischaemic attack, or systemic embolism, left ventricular ejection fraction < 40%, symptomatic heart failure, ≥New York Heart Association Class 2, age ≥75 years, age ≥65 years associated with one of the following: diabetes mellitus, coronary artery disease or hypertension. *VTE AFTER ORTHOPAEDIC SURGERY:* Prevention of venous thromboembolic events in patients who have undergone major orthopaedic surgery. *DVT/PE:* Treatment of acute deep vein thrombosis (DVT) and/or pulmonary embolism (PE) and prevention of related death following treatment with a parenteral anticoagulant for at least 5 days. Prevention of recurrent DVT and/or PE and related death. **DOSAGE:** *SPAF:* Usually 150 mg twice daily. Patients aged ≥80 years: 110mg twice daily. Patients aged 75 to 80 years or those with moderate renal impairment (CrCl 30-50 mL/min) with low thromboembolic risk and high bleeding risk: consider 110 mg twice daily. *VTE AFTER ORTHOPAEDIC SURGERY:* Initially 110 mg followed by 220 mg once daily thereafter for a total of 10 days for knee replacement surgery or a total of 28 – 35 days for hip replacement surgery. Patients with moderate renal impairment (CrCl 30-50 mL/min): two 75 mg capsules once daily. *ACUTE DVT/PE:* 150 mg twice daily following treatment with a parenteral anticoagulant for at least 5 days. Therapy should be continued for up to 6 months. Patients aged ≥80 years: 110mg twice daily. Patients aged 75 to 80 years or those with moderate renal impairment (CrCl 30-50 mL/min) with low thromboembolic risk and high bleeding risk: consider 110 mg twice daily. *RECURRENT DVT/PE:* 150 mg twice daily. Therapy could be continued life-long depending on the individual patient risk. Patients aged ≥80 years: 110mg twice daily. Patients aged 75 to 80 years or those with moderate renal impairment (CrCl 30-50 mL/min) with low thromboembolic risk and high bleeding risk: consider 110 mg twice daily. **ADMINISTRATION:** Take capsule whole with a glass of water, with or without food. Do not chew or open capsule. Assess renal function: prior to treatment initiation, in clinical situations that could lead to renal function decline, and at least once a year in patients with moderate renal impairment (CrCl 30-50 mL/min). **CONTRAINDICATIONS:** Known hypersensitivity to dabigatran or dabigatran etexilate or to one of the excipients. Severe renal impairment (CrCl < 30 mL/min). Haemorrhagic manifestations, patients with a bleeding diathesis, or patients with spontaneous or pharmacological impairment of haemostasis. Organ lesions at risk of clinically significant bleeding, including haemorrhagic stroke within the last 6 months. Concomitant treatment with systemic ketoconazole. Prosthetic heart valve replacement. **WARNINGS AND PRECAUTIONS:** Haemorrhagic risk*: moderate renal impairment (CrCl 30-50 mL/min), acetylsalicylic acid, NSAIDs, clopidogrel, congenital or acquired coagulation disorders, thrombocytopenia or functional platelet defects, active ulcerative gastrointestinal disease, recent gastrointestinal bleeding, recent biopsy or major trauma, recent intracranial haemorrhage, brain, spinal or ophthalmic surgery, bacterial endocarditis, age ≥75 years. Concomitant administration with: unfractionated heparins and heparin derivatives, low molecular weight heparins, fondaparinux, desirudin, thrombolytic agents, GPIIb/IIIa receptor antagonists, ticlopidine, dextran, sulfinpyrazone, rivaroxaban, prasugrel, ticagrelor, vitamin K antagonists, selective serotonin re-uptake inhibitors, selective serotonin norepinephrine re uptake inhibitors and the P-gp inhibitors (e.g. amiodarone, verapamil, quinidine, dronedarone, clarithromycin), itraconazole, tacrolimus, ciclosporin, ritonavir, tipranavir, nelfinavir, saquinavir and glecaprevir/pibrentasvir fixed-dose combination, P-gp inducers (e.g. rifampicin). Patients with antiphospholipid syndrome. Elevated liver enzymes >2 ULN. Surgical interventions may require temporary discontinuation of PRADAXA®. Pregnancy. Lactation. Children. Patients < 50 kg. * *For situation of life-threatening/uncontrolled bleeding, and in case of emergency surgery/urgent procedures when rapid reversal of the anticoagulation effects of PRADAXA is required, the specific reversal agent (PRAXBIND, idarucizumab) is available.* **ADVERSE EFFECTS:** Common: Bleeding and signs of bleeding, anaemia, epistaxis, gastrointestinal haemorrhage, abdominal pain, diarrhoea, dyspepsia, nausea, hepatic function abnormal, urogenital haemorrhage. Serious: Major or severe bleeding, thrombocytopenia, drug hypersensitivity, angioedema, intracranial haemorrhage, haemoptysis. Others, see full Data Sheet. **INTERACTIONS:** See CONTRAINDICATIONS and WARNINGS AND PRECAUTIONS above. **ACTIONS:** Dabigatran is a potent, competitive, reversible direct thrombin inhibitor and is the main active principle in plasma. Dabigatran prolongs the aPTT, ECT and TT.

PRESCRIPTION MEDICINE
PRADAXA® is fully funded with no special authority
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PRAXBIND® (idarucizumab, rch) 50 mg/mL solution for injection/infusion. Before prescribing, please review the full Data Sheet which is available on request from Boehringer Ingelheim or from http://www.medsafe.govt.nz/profs/datasheet/dsform.asp

INDICATION: Specific reversal agent for dabigatran, indicated in patients treated with PRADAXA (dabigatran etexilate) when rapid reversal of the anticoagulant effects of dabigatran is required: for emergency surgery/urgent procedures, and in life-threatening or uncontrolled bleeding. **DOSAGE:** The recommended dose is 5 g. Two 50 mL vials (2 x 2.5 g) constitute one complete dose. **ADMINISTRATION:** The complete dose of 5 g is administered intravenously, as two consecutive infusions over 5 to 10 minutes each or as a bolus injection. For instructions for use / handling and restarting antithrombotic therapy, see full Data Sheet. **CONTRAINDICATIONS:** None. **WARNINGS AND PRECAUTIONS:** Idarucizumab will not reverse the effects of other anticoagulants. Known hypersensitivity (weighed against potential benefit of emergency treatment) – discontinue PRAXBIND immediately in case of anaphylactic reaction or other serious allergic reaction. Hereditary fructose intolerance, controlled sodium diet. Pregnancy. Lactation. Children. Trade name and batch number should be recorded in patient file to improve traceability. See full Data Sheet. **ADVERSE EFFECTS:** No adverse events causally related to PRAXBIND have been identified. **INTERACTIONS:** Clinically relevant interactions with other medicinal products are not expected. **ACTIONS:** Idarucizumab is a humanised monoclonal antibody fragment (Fab) molecule derived from an IgG1 isotype antibody molecule, directed against the thrombin inhibitor dabigatran.

PRESCRIPTION MEDICINE
PRAXBIND® is a funded medicine – Restrictions apply: Pharmaceutical Schedule, Hospital Medicines List

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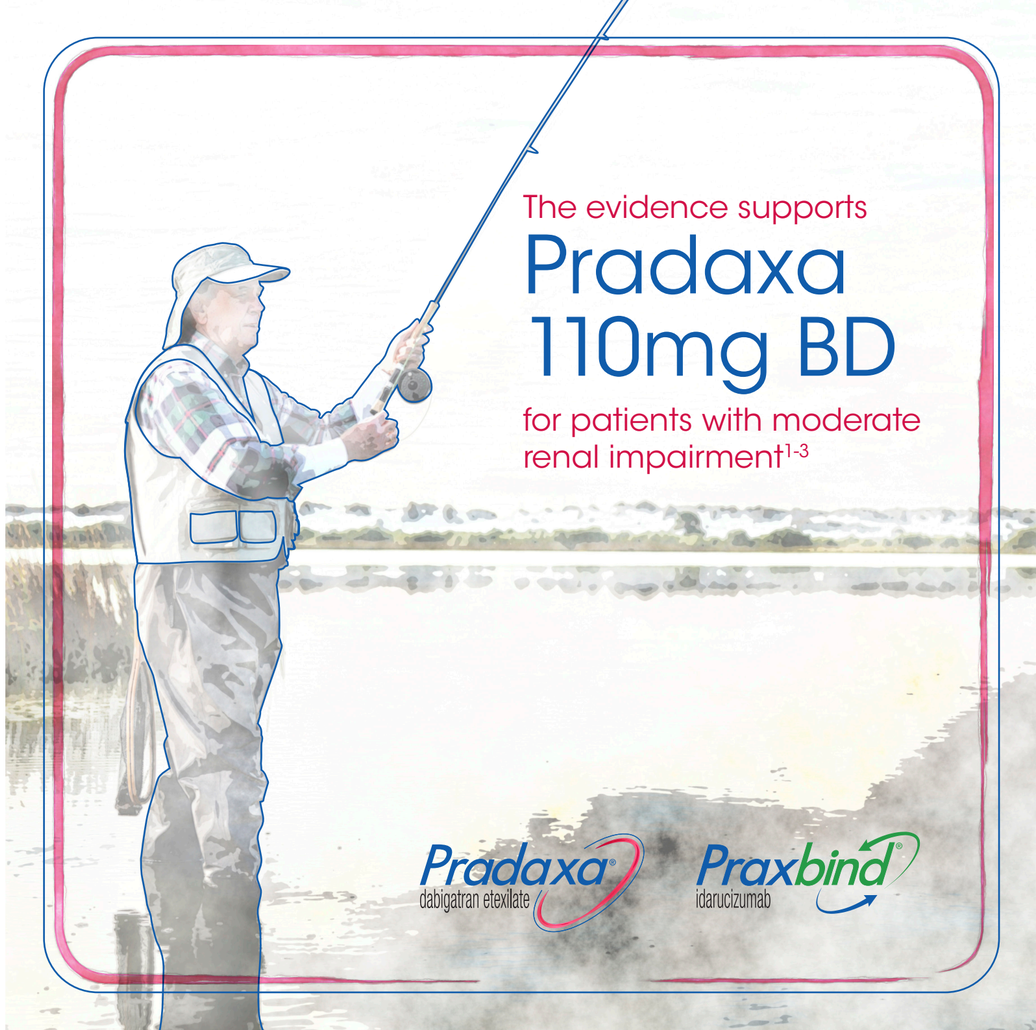


The evidence supports

Pradaxa 110mg BD

for patients with moderate renal impairment[1-3]

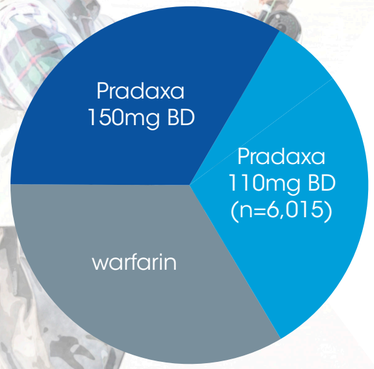
Pradaxa® dabigatran etexilate

Praxbind® idarucizumab

RE-LY®

Consider Pradaxa 110mg BD[1,3-5]
(for patients with moderate renal impairment)

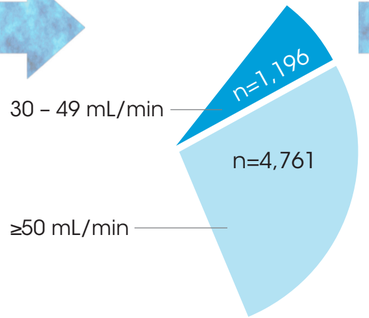
Pradaxa 110mg BD
vs warfarin (CrCl 30-49ml/min)



Enrolled 18,113 patients

"The treatment groups were well balanced"[3]

Creatinine Clearance



60% Intracranial Haemorrhage
HR 0.40 (CI 0.20 – 0.80)

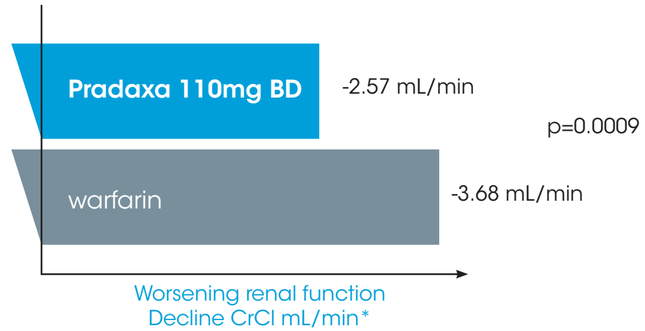
✓ Similar Efficacy
Stroke/systemic embolism
HR 0.85 (CI 0.59 – 1.24)

✓ Similar Safety
Major Bleeding
HR 0.99 (CI 0.77 – 1.28)

Assessed using Cockcroft-Gault

These results are consistent with the full cohort of Pradaxa 110mg BD patients from RE-LY.[3-5] Stroke/SE (HR 0.89, CI 0.73-1.09), Major bleeding (HR 0.80, CI 0.70-0.93) and ICH (HR 0.30, CI 0.19-0.45)

Change in renal function over time[7]
(up to 30-months were evaluated)



Assessed using CKD-EPI*

"We found that dabigratran treatment was associated with a smaller decline in renal function over time compared with warfarin"[7]

*CKD-EPI: Chronic Kidney Disease Epidemiology Collaboration