Prescribing Information (SPAF and DVT/PE Ireland)

PRADAXA® (dabigatran etexilate)

Capsules containing 110 mg or 150 mg dabigatran etexilate (as mesilate) **Action**: Direct thrombin inhibitor **Indications**: Prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation (NVAF) with one or more risk factors (SPAF), such as prior stroke, or transient ischaemic attack (TIA); age ≥ 75 years; heart failure (NYHA-Class ≥ II); diabetes mellitus; hypertension. Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT and PE in adults (DVT/PE). **Dose and Administration**: Renal function should be assessed by calculating creatinine clearance (CrCL) prior to initiation to exclude patients with severe renal impairment (CrCL < 30 mL/min). SPAF: Recommended daily dose 300 mg taken as one 150 mg capsule twice daily. Therapy should be continued long term. DVT/PE: Recommended daily dose 300 mg taken as one 150 mg capsule twice daily following treatment with parenteral anticoagulant for at least 5 days. Duration of treatment should be individualised after careful assessment of the treatment benefit against risk for bleeding. Short duration of therapy (at least three months) should be based on transient risk factors (e.g. recent surgery, trauma, immobilisation) and longer durations should be based on permanent risk factors or idiopathic DVT or PE. In case of intolerability to dabigatran, patients should be instructed to immediately consult their doctor. For patients aged 80 years or above, or those receiving concomitant verapamil, the recommended daily dose is Pradaxa 220 mg taken as 110 mg twice daily. Pradaxa and verapamil should be taken at the same time. For the following patient groups, the daily dose of 300 mg or 220 mg should be selected based on an individual assessment of the thromboembolic risk and risk of bleeding: aged 75 – 80 years; with moderate renal impairment (CrCL 30-50 mL/min); with gastritis, oesophagitis or gastroesophageal reflux; other risk of increased bleeding. Close clinical surveillance is recommended in patients with renal impairment. Use is contraindicated in patients with severe renal impairment (CrCL < 30 mL/min). In all patients and especially the elderly (> 75 years) assess renal function by calculating CrCL prior to initiation to exclude patients with severe renal impairment. Renal function should also be assessed when a decline in renal function is suspected. Additionally in patients > 75 years or with mild to moderate renal impairment, renal function should also be assessed at least once a year or more frequently as needed in certain clinical situations when it is suspected that the renal function could decline or deteriorate. Patients with an increased risk of bleeding: closely monitor clinically looking for signs of bleeding or anaemia. A coagulation test may help identify increased risk patients. No dose adjustment required but close clinical surveillance in patients < 50 kg. If switching from Pradaxa to parenteral anticoagulant wait 12 hours after the last dose of Pradaxa; if switching from parenteral anticoagulant to Pradaxa discontinue the parenteral anticoagulant and start Pradaxa 0-2 hours prior to the time that the next dose of the alternate therapy would be due, or at the time of discontinuation in case of continuous treatment; if switching from Pradaxa to VKA adjust the starting time of the VKA based on CrCL; if switching from VKA to Pradaxa stop VKA and give Pradaxa once INR < 2.0. Cardioversion (SPAF): patients can stay on Pradaxa whilst being cardioverted. Catheter ablation for atrial fibrillation (SPAF): Can be conducted in patients on 150 mg twice daily Pradaxa treatment - treatment does not need to be interrupted. No data available for 110 mg twice daily Pradaxa treatment. Percutaneous coronary intervention (PCI) with stenting (SPAF): Patients with non valvular atrial fibrillation who undergo a PCI with stenting can be treated with Pradaxa in combination with antiplatelets after haemostasis is achieved. No relevant use of Pradaxa in the paediatric population in the SPAF indication. In DVT/PE indication safety and efficacy of Pradaxa in ages less than 18 years have not been established. Pradaxa is for oral use and can be taken with or without food. Pradaxa should be swallowed as a whole with a glass of water to facilitate delivery to the stomach. Patients should be instructed not to open the capsule as this may increase the risk of bleeding. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients; severe renal impairment (CrCL < 30 mL/min); active clinically significant bleeding; lesion or condition, if considered a significant risk factor for major bleeding. This may include current or recent gastrointestinal ulceration, presence of malignant neoplasms at high risk of bleeding, recent brain or spinal injury, recent brain, spinal or ophthalmic surgery, recent intracranial haemorrhage, known or suspected oesophageal varices, arteriovenous malformations, vascular aneurysms or major intraspinal or intracerebral vascular abnormalities; concomitant treatment with any other anticoagulants e.g. unfractionated heparin (UFH), low molecular weight heparins (enoxaparin, dalteparin etc), heparin derivatives (fondaparinux etc), oral anticoagulants (warfarin, rivaroxaban, apixaban etc) except under specific circumstances. These are switching anticoagulant therapy, when UFH is given at doses necessary to maintain an open central venous or arterial catheter or when UFH is given during catheter ablation for atrial fibrillation; hepatic impairment or liver disease expected to have any impact on survival; concomitant treatment with the following strong P- glycoprotein (P-gp) inhibitors: systemic ketoconazole, cyclosporine, itraconazole, dronedarone and the fixed-dose combination glecaprevir/pibrentasvir; prosthetic heart valves requiring anticoagulant treatment. **Warnings and Precautions:** Not recommended if liver enzymes > 2 ULN. Haemorrhagic risk: Close clinical surveillance (signs of bleeding or anaemia) is recommended throughout the treatment period, especially if haemorrhagic risk is increased or risk factors combined. For situations of life-threatening or uncontrolled bleeding, when rapid reversal of anticoagulation effect of dabigatran is required, the specific reversal agent (Praxbind, idarucizumab) is available. Factors which may increase haemorrhagic risk: age ≥ 75 years; moderate renal impairment (CrCL 30 – 50 mL/min); P-glycoprotein inhibitor co- medication; body weight < 50 kg; acetylsalicylic acid (aspirin) and other platelet aggregation inhibitors such as clopidogrel; NSAID; selective serotonin re-uptake inhibitors (SSRIs) or selective serotonin norepinephrine re-uptake inhibitors (SNRIs); other medicinal products which may impair haemostasis; diseases/procedures associated with a risk of bleeding such as coagulation disorders, thrombocytopenia or functional platelet defects, recent biopsy, major trauma, bacterial endocarditis, oesophagitis, gastritis or gastroesophageal reflux. The measurement of dabigatran related anticoagulation may be helpful to detect excessive high exposure to dabigatran in the presence of additional risk factors. Patients who develop acute renal failure must discontinue Pradaxa.

When severe bleeding occurs, discontinue treatment, investigate the source of the bleeding and use of the specific reversal agent Praxbind (idarucizumab) may be considered. Avoid or use with caution medicinal products which may increase the risk of haemorrhage. The use of fibrinolytic medicinal products for the treatment of acute ischaemic stroke may be considered if the patient presents with a dTT, ECT or aPTT not exceeding the upper limit of normal (ULN) according to the local reference range. Avoid concomitant administration with P-gp inducers. Patients on dabigatran etexilate who undergo surgery or invasive procedures are at increased risk for bleeding therefore surgical interventions may require the temporary discontinuation of dabigatran etexilate. In emergency surgery or urgent procedures, when rapid reversal of the anticoagulation effect is required the specific reversal agent (Praxbind, idarucizumab) to dabigatran is available. Prescribers should consult the Summary of Product Characteristics for further information relating to surgery and interventions. Procedures such as spinal anaesthesia may require complete haemostatic function. The risk of spinal or epidural haematoma may be increased in cases of traumatic or repeated puncture and by the prolonged use of epidural catheters. After removal of a catheter, an interval of at least 2 hours should elapse before the administration of the first dose of dabigatran etexilate; these patients require frequent observation for neurological signs and symptoms of spinal or epidural haematoma. Treat with caution patients at high surgical mortality risk and with intrinsic risk factors for thromboembolic events. Direct acting Oral Anticoagulants (DOACs) including dabigatran etexilate are not recommended for patients with a history of thrombosis who are diagnosed with antiphospholipid syndrome. Myocardial infarction. Efficacy and safety have not been established for DVT/PE patients with active cancer. **Interactions**: P-gp inhibitors - close clinical surveillance and dose reductions may be required (see above): contraindicated – ketoconazole, dronedarone, itraconazole, cyclosporine, glecaprevir/pibrentasvir; not recommended – tacrolimus; use with caution – verapamil, amiodarone, quinidine, clarithromycin, ticagrelor, posaconazole. P-gp inducers e.g. rifampicin, St John's wort, carbamazepine or phenytoin - use should be avoided. Protease inhibitors e.g. ritonavir and its combinations with other protease inhibitors – use not recommended. Anticoagulants and antiplatelet aggregation medicinal products. SSRIs or SNRIs. Pantoprazole and other proton-pump inhibitors (PPI) were co-administered with Pradaxa in clinical trials and concomitant PPI treatment did not appear to reduce the efficacy of Pradaxa. Ranitidine administration together with Pradaxa had no clinically relevant effect on the extent of absorption of dabigatran. Dabigatran etexilate and dabigatran are not metabolised by cytochrome CYP450 system, therefore related medicinal product interactions not expected. **Fertility, pregnancy and lactation**: Avoid pregnancy during treatment. Do not use in pregnancy unless clearly necessary. Discontinue breast-feeding during treatment. **Undesirable effects**: Most commonly reported adverse reactions are bleedings occurring in total in approximately 16.6 % in patients with atrial fibrillation treated for the prevention of stroke and systemic embolism (SEE) and 14.4 % in patients treated for DVT/PE. Bleeding occurred in 19.4% of patients in DVT/PE prevention trial RE-MEDY and in 10.5% of patients in DVT/PE prevention trial RE-SONATE. Adverse reactions identified from the study in prevention of thromboembolic stroke and systemic embolism in patients with atrial fibrillation and the studies in DVT/PE treatment and in DVT/PE prevention are listed with frequency using the following convention: common (≥ 1/100 to < 1/10), uncommon (≥ 1/1,000 to < 1/100), rare (≥ 1/10,000 to < 1/1,000), not known (cannot be estimated from the available data). *Stroke and SEE*: Common: anaemia; epistaxis; gastrointestinal haemorrhage; abdominal pain; diarrhoea; dyspepsia; nausea; skin haemorrhage; genitourological haemorrhage, including haematuria. Uncommon: haemoglobin decreased; thrombocytopenia; drug hypersensitivity; rash; pruritus; intracranial haemorrhage; haematoma; haemorrhage; haemoptysis; rectal haemorrhage; haemorrhoidal haemorrhage; gastrointestinal ulcer; gastroesophagitis; gastroesophageal reflux disease; vomiting; dysphagia; hepatic function abnormal/ liver function test abnormal; alanine aminotransferase increased; aspartate aminotransferase increased. Rare: haematocrit decreased; anaphylactic reaction; angioedema; urticaria; hepatic enzyme increased; hyperbilirubinaemia; haemarthrosis; injection site haemorrhage; catheter site haemorrhage; traumatic haemorrhage; incision site haemorrhage. Not known: neutropenia; agranulocytosis; bronchospasm; alopecia. *DVT/PE*: Common: epistaxis; gastrointestinal haemorrhage; dyspepsia; rectal haemorrhage; skin haemorrhage; genitourological haemorrhage, including haematuria. Uncommon: anaemia; drug hypersensitivity; rash; pruritus; haematoma; haemorrhage; haemoptysis; abdominal pain; diarrhoea; nausea; haemorrhoidal haemorrhage; gastrointestinal ulcer; gastroesophagitis; gastroesophageal reflux disease; vomiting; hepatic function abnormal/ liver function test abnormal; alanine aminotransferase increased; aspartate aminotransferase increased; hepatic enzyme increased; haemarthrosis; traumatic haemorrhage. Rare: thrombocytopenia; anaphylactic reaction; angioedema; urticaria; intracranial haemorrhage; dysphagia; injection site haemorrhage; catheter site haemorrhage; incision site haemorrhage. Not known: haemoglobin decreased; haematocrit decreased; neutropenia; agranulocytosis; bronchospasm; hyperbilirubinaemia; alopecia. Prescribers should consult the Summary of Product Characteristics for further information on side effects. **Pack sizes:** *110 mg* 60 capsules, *150 mg* 60 capsules **Legal category** POM **MA numbers**: *110 mg* EU/1/08/442/007 (60 capsules); *150 mg* EU/1/08/442/011 (60 capsules) **Marketing Authorisation Holder**: Boehringer Ingelheim International GmbH, Binger Str. 173, D-55216 Ingelheim am Rhein, Germany. Prescribers should consult the Summary of Product Characteristics for full prescribing information. Additional information is available on request from Boehringer Ingelheim Ireland Ltd, The Crescent Building, Northwood, Santry, Dublin 9. **Prepared in** July 2020.

Adverse events should be reported to the Health Products Regulatory Authority at www.hpra.ie or by email to medsafety@hpra.ie
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Pradaxa®
dabigatran etexilate

Prescribing information for pVTEp and Praxbind® (idarucizumab) can be found on the following pages

Prescribing Information (pVTEp Ireland)

PRADAXA® (dabigatran etexilate)

Capsules containing 75 mg or 110 mg dabigatran etexilate (as mesilate) **Action**: Direct thrombin inhibitor **Indication**: Primary prevention of venous thromboembolic events in adult patients who have undergone elective total hip or knee replacement surgery. **Dose and Administration**: Renal function should be assessed by calculating creatinine clearance (CrCL) prior to initiation to exclude patients with severe renal impairment (CrCL < 30 mL/min). Recommended dose is 220 mg once daily orally taken as 2 capsules of 110 mg. Initiate treatment within 1-4 hours of completed surgery with a single capsule continuing with 2 capsules once daily for a total of 10 days (knee replacement surgery) or 28 – 35 days (hip replacement surgery). Delay initiation of treatment if haemostasis is not secured. If treatment is not started on the day of surgery, initiate with 2 capsules once daily. For the following groups the recommended daily dose of Pradaxa is 150 mg taken once daily as 2 capsules of 75 mg: patients with moderate renal impairment (CrCL 30-50 mL/min); patients who receive concomitant verapamil, amiodarone, quinidine; patients aged 75 or above. In patients with moderate renal impairment and concomitant verapamil, consider 75 mg daily. Pradaxa is contraindicated in severe renal impairment (CrCL < 30 mL/min). In all patients and especially the elderly (> 75 years) assess renal function by calculating CrCL prior to initiation to exclude patients with severe renal impairment. Renal function should also be assessed while on treatment in certain clinical situations when it is suspected that renal function could decline or deteriorate. No dose adjustment required but close clinical surveillance in patients < 50 kg or > 110 kg. If switching from Pradaxa to parenteral anticoagulant wait 24 hours after the last dose of Pradaxa; if switching from parenteral anticoagulant to Pradaxa, discontinue the parenteral anticoagulant and start Pradaxa 0-2 hours prior to the time that the next dose of the alternate therapy would be due, or at the time of discontinuation in case of continuous treatment. No relevant use of Pradaxa in the paediatric population in the indication. Pradaxa is for oral use and can be taken with or without food. Pradaxa should be swallowed as a whole with a glass of water, to facilitate delivery to the stomach. Patients should be instructed not to open the capsule as this may increase the risk of bleeding. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients; severe renal impairment (CrCL < 30 mL/min); active clinically significant bleeding; lesion or condition, if considered a significant risk factor for major bleeding. This may include current or recent gastrointestinal ulceration, presence of malignant neoplasms at high risk of bleeding, recent brain or spinal injury, recent brain, spinal or ophthalmic surgery, recent intracranial haemorrhage, known or suspected oesophageal varices, arteriovenous malformations, vascular aneurysms or major intraspinal or intracerebral vascular abnormalities; concomitant treatment with any other anticoagulants e.g. unfractionated heparin (UFH), low molecular weight heparins (enoxaparin, dalteparin etc), heparin derivatives (fondaparinux etc), oral anticoagulants (warfarin, rivaroxaban, apixaban etc) except under specific circumstances. These are switching anticoagulant therapy, when UFH is given at doses necessary to maintain an open central venous or arterial catheter or when UFH is given during catheter ablation for atrial fibrillation; hepatic impairment or liver disease expected to have any impact on survival; concomitant treatment with the following strong P-glycoprotein (P-gp) inhibitors: systemic ketoconazole, cyclosporine, itraconazole, dronedarone and the fixed-dose combination glecaprevir/pibrentasvir; prosthetic heart valves requiring anticoagulant treatment. **Warnings and Precautions:** Not recommended if liver enzymes > 2 ULN. Haemorrhagic risk: Close clinical surveillance (signs of bleeding or anaemia) is recommended throughout the treatment period, especially if haemorrhagic risk is increased or risk factors combined. For situations of life-threatening or uncontrolled bleeding, when rapid reversal of anticoagulation effect of dabigatran is required, the specific reversal agent (Praxbind, idarucizumab) is available. Factors which may increase haemorrhagic risk: age ≥ 75 years; moderate renal impairment (CrCL 30 – 50 mL/min); P-glycoprotein inhibitor co-medication; body weight < 50 kg; acetylsalicylic acid (aspirin) and other platelet aggregation inhibitors such as clopidogrel; NSAID; selective serotonin re-uptake inhibitors (SSRIs) or selective serotonin norepinephrine re-uptake inhibitors (SNRIs); other medicinal products which may impair haemostasis; diseases/procedures associated with a risk of bleeding such as coagulation disorders, thrombocytopenia or functional platelet defects, recent biopsy, major trauma, bacterial endocarditis, oesophagitis, gastritis or gastroesophageal reflux. The measurement of dabigatran related anticoagulation may be helpful to detect excessive high exposure to dabigatran in the presence of additional risk factors. Patients who develop acute renal failure must discontinue Pradaxa. When severe bleeding occurs, discontinue treatment, investigate the source of the bleeding and use of the specific reversal agent (Praxbind, idarucizumab) may be considered. Avoid or use with caution medicinal products which may increase the risk of haemorrhage. The use of fibrinolytic medicinal products for the treatment of acute ischaemic stroke may be considered if the patient presents with a dTT, ECT or aPTT not exceeding the upper level of normal (ULN) according to the local reference range. Avoid concomitant administration with P-gp inducers. Patients on dabigatran etexilate who undergo surgery or invasive procedures are at increased risk for bleeding therefore surgical interventions may require the temporary discontinuation of dabigatran etexilate. In emergency surgery or urgent procedures, when rapid reversal of the anticoagulation effect is required the specific reversal agent (Praxbind, idarucizumab) to dabigatran is available. Prescribers should consult the Summary of Product Characteristics for further information relating to surgery and interventions. Procedures such as spinal anaesthesia may require complete haemostatic function. The risk of spinal or epidural haematoma may be increased in cases of traumatic or repeated puncture and by the prolonged use of epidural catheters. After removal of a catheter, an interval of at least 2 hours should elapse before the administration of the first dose of dabigatran etexilate; these patients require frequent observation for neurological signs and symptoms of spinal or epidural haematoma. Treat with caution patients at high surgical mortality risk and with intrinsic risk factors for thromboembolic events. No data on the use of Pradaxa in patients undergoing hip fracture surgery, therefore treatment not recommended. Direct acting Oral Anticoagulants (DOACs) including dabigatran etexilate are not recommended for patients with a history of thrombosis who are diagnosed with antiphospholipid syndrome. **Interactions**: P-gp inhibitors - close clinical surveillance and dose reductions may be required (see above): contraindicated – ketoconazole, dronedarone, itraconazole, cyclosporine, glecaprevir/pibrentasvir; not recommended – tacrolimus; use with caution – verapamil, amiodarone, quinidine, clarithromycin, ticagrelor, posaconazole. P-gp inducers e.g. rifampicin, St John's wort, carbamazepine or phenytoin - use should be avoided. Protease inhibitors e.g. ritonavir and its combinations with other protease inhibitors – use not recommended. Anticoagulants and antiplatelet aggregation medicinal products. SSRIs or SNRIs. Pantoprazole and other proton-pump inhibitors (PPI) were co-administered with Pradaxa in clinical trials and concomitant PPI treatment did not appear to reduce the efficacy of Pradaxa. Ranitidine administration together with Pradaxa had no clinically relevant effect on the extent of absorption of dabigatran. Dabigatran etexilate and dabigatran are not metabolised by cytochrome CYP450 system, therefore related medicinal product interactions not expected. **Fertility, pregnancy and lactation**: Avoid pregnancy during treatment. Do not use in pregnancy unless clearly necessary. Discontinue breast-feeding during treatment. **Undesirable effects**: Most commonly reported adverse reactions are bleedings occurring in total in approximately 14% of patients treated short-term for elective hip or knee replacement surgery; major bleeds, including wound site bleedings < 2%. Adverse reactions are listed with frequency using the following convention: common (≥ 1/100 to < 1/10), uncommon (≥ 1/1,000 to < 1/100), rare (≥ 1/10,000 to < 1/1,000), not known (cannot be estimated from the available data). Common: haemoglobin decreased; hepatic function abnormal/liver function test abnormal. Uncommon: anaemia; haematocrit decreased; drug hypersensitivity; haematoma; wound haemorrhage; epistaxis; gastrointestinal haemorrhage; rectal haemorrhage; haemorrhoidal haemorrhage; diarrhoea; nausea; vomiting; alanine aminotransferase increased; aspartate aminotransferase increased; hepatic enzyme increased; hyperbilirubinaemia; skin haemorrhage; haemarthrosis; genitourological haemorrhage, including haematuria; traumatic haemorrhage; post procedural haematoma; post procedural haemorrhage; post procedural discharge; wound secretion. Rare: thrombocytopenia; anaphylactic reaction; angioedema; urticaria; rash; pruritus; intracranial haemorrhage; haemorrhage; haemoptysis; gastrointestinal ulcer, including oesophageal ulcer; gastroesophagitis; gastroesophageal reflux disease; abdominal pain; dyspepsia; dysphagia; injection site haemorrhage; catheter site haemorrhage; bloody discharge; incision site haemorrhage; anaemia postoperative; wound drainage; post procedural drainage. Not known: neutropenia; agranulocytosis; bronchospasm; alopecia. Prescribers should consult the Summary of Product Characteristics for further information on side effects. **Pack sizes:** *75 mg* 10 and 60 capsules *110 mg* 10 and 60 capsules **Legal category** POM **MA numbers**: *75 mg* EU/1/08/442/001 (10 capsules); EU/1/08/442/003 (60 capsules) *110 mg* EU/1/08/442/005 (10 capsules); EU/1/08/442/007 (60 capsules) **Marketing Authorisation Holder**: Boehringer Ingelheim International GmbH, Binger Str. 173, D-55216 Ingelheim am Rhein, Germany. Prescribers should consult the Summary of Product Characteristics for full prescribing information. Additional information is available on request from Boehringer Ingelheim Ireland Ltd, The Crescent Building, Northwood, Santry, Dublin 9. **Prepared in** July 2020

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Pradaxa® dabigatran etexilate

Prescribing information for Praxbind® (idarucizumab) can be found on the following page

PC-IE-100321 V6 | October 2021

Prescribing Information (Ireland)

PRAXBIND® (idarucizumab) 2.5 g/50 mL, solution for injection/infusion
Vials containing 2.5 g idarucizumab in 50 mL solution for injection/infusion. **Indication:** Praxbind 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. **Dose and Administration:** Restricted to hospital use only. Recommended dose is 5 g (2 vials of 2.5 g/ 50 mL), administered intravenously as two consecutive infusions over 5 to 10 minutes each or as a bolus injection. Administration of a second 5 g dose may be considered in the following situations: recurrence of clinically relevant bleeding together with prolonged clotting times; if potential re-bleeding would be life-threatening and prolonged clotting times are observed; patients require a second emergency surgery/urgent procedure and have prolonged clotting times. Restarting antithrombotic therapy: if the patient is clinically stable and adequate haemostasis has been achieved following administration of idarucizumab, Pradaxa (dabigatran etexilate) treatment can be re-initiated after 24 hours; other antithrombotic therapy (e.g. low-molecular weight heparin) can be started at any time. No dose adjustment is required in patients with renal or hepatic impairment or in elderly patients aged 65 years and above. Safety and efficacy in children below the age of 18 years have not been established. **Contraindications:** None. **Warnings and Precautions:** Idarucizumab binds specifically to dabigatran and reverses its anticoagulant effect. It will not reverse the effects of other anticoagulants. Treatment can be used in conjunction with medically appropriate standard supportive measures. In patients with known hypersensitivity (e.g. anaphylactoid reaction) to idarucizumab or to any of the excipients the risk of using Praxbind needs to be weighed cautiously against the potential benefit of the emergency treatment, discontinue use if an anaphylactic reaction or other serious reaction occurs. The recommended dose of Praxbind contains 4 g sorbitol as an excipient. In patients with hereditary fructose intolerance, parenteral administration of sorbitol has been associated with reports of hypoglycaemia, hypophosphatemia, metabolic acidosis, increase in uric acid, acute liver failure with breakdown of excretory and synthetic function, and death. Consequently, in these patients the risk of treatment with Praxbind must be weighed against the potential benefit and if Praxbind is administered intensified medical care during and within 24 hours of exposure is required. Reversing dabigatran therapy exposes patients to the thrombotic risk of their underlying disease. To reduce this risk resumption of anticoagulant therapy should be considered as soon as medically appropriate. Contains 2.2 mmol (50 mg) sodium per dose. Praxbind causes transient proteinuria which is not indicative of renal damage but which should be taken into account for urine testing. **Interactions:** No formal interaction studies have been performed. Based on pharmacokinetic properties and high specificity in binding to dabigatran clinically relevant interactions with other medicinal products are considered unlikely. **Fertility, Pregnancy and Lactation:** There are no data for use in pregnant women. Praxbind may be used during pregnancy, if the expected clinical benefit outweighs the potential risks. There are no data on the effect on fertility. It is unknown whether idarucizumab/ metabolites are excreted in human milk. **Undesirable effects:** No adverse reactions have been identified **Pack sizes:** Carton containing 2 vials **Legal category:** POM **MA numbers:** EU/1/15/1056/001 **Marketing Authorisation Holder:** Boehringer Ingelheim International GmbH, Binger Str. 173, D-55216 Ingelheim am Rhein, Germany. Prescribers should consult the Summary of Product Characteristics for full prescribing information. Additional information is available on request from Boehringer Ingelheim Ireland Ltd, The Crescent Building, Northwood, Santry, Dublin 9. **Prepared in** October 2020

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Praxbind®
idarucizumab