Prescribing Information (UK) 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 and NHS price:** Carton containing 2 vials £2,400. **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. **Prepared in** October 2020

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).

PC-UK-101747 V3 | October 2020

Praxbind® idarucizumab