HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use PRAXBIND safely and effectively. See full prescribing information for PRAXBIND.

PRAXBIND® (idarucizumab) injection, for intravenous use

Initial U.S. Approval: 2015

INDICATIONS AND USAGE

PRAXBIND is a humanized monoclonal antibody fragment (Fab) indicated in patients treated with Pradaxa® when reversal of the anticoagulant effects of dabigatran is needed:

- For emergency surgery/urgent procedures
- In life-threatening or uncontrolled bleeding (1)

This indication is approved under accelerated approval based on a reduction in unbound dabigatran and normalization of coagulation parameters in healthy volunteers. Continued approval for this indication may be contingent upon the results of an ongoing cohort case series study. (1)

DOSAGE AND ADMINISTRATION

For intravenous use only.

- The recommended dose of PRAXBIND is 5 g, provided as two separate vials each containing 2.5 g/50 mL idarucizumab. (2.1)
- There is limited data to support administration of an additional 5 g of PRAXBIND. (2.1)

DOSAGE FORMS AND STRENGTHS

Injection: 2.5 g/50 mL solution in a single-use vial (3)

CONTRAINDICATIONS

- None (4)

WARNINGS AND PRECAUTIONS

- *Thromboembolic Risk:* Reversing dabigatran therapy exposes patients to the thrombotic risk of their underlying disease. Resume anticoagulant therapy as soon as medically appropriate. (2.4, 5.1)
- *Re-elevation of Coagulation Parameters:* In patients with elevated coagulation parameters and reappearance of clinically relevant bleeding or requiring a second emergency surgery/urgent procedure, an additional 5 g dose of PRAXBIND may be considered. (5.2)
- *Hypersensitivity reactions:* Discontinue administration and evaluate. (5.3)
- *Risks of Serious Adverse Reactions in Patients with Hereditary Fructose Intolerance due to Sorbitol Excipient:* Patients with hereditary fructose intolerance may be at risk of adverse reactions. (5.4)

ADVERSE REACTIONS

- In healthy volunteers, the most frequently reported adverse reactions in greater than or equal to 5% of subjects treated with idarucizumab was headache. (6.1)
- In patients, the most frequently reported adverse reactions in greater than or equal to 5% of patients treated with idarucizumab were hypokalemia, delirium, constipation, pyrexia, and pneumonia. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Boehringer Ingelheim Pharmaceuticals, Inc. at (800) 542-6257 or (800) 459-9906 TTY or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch*.

See 17 for PATIENT COUNSELING INFORMATION.

Revised: 10/2015

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FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

PRAXBIND is indicated in patients treated with Pradaxa when reversal of the anticoagulant effects of dabigatran is needed:

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

This indication is approved under accelerated approval based on a reduction in unbound dabigatran and normalization of coagulation parameters in healthy volunteers *[see Clinical Studies (14)]*. Continued approval for this indication may be contingent upon the results of an ongoing cohort case series study.

2 DOSAGE AND ADMINISTRATION

For intravenous use only.

2.1 Recommended Dose

The recommended dose of PRAXBIND is 5 g, provided as two separate vials each containing 2.5 g/50 mL idarucizumab (see Figure 1).

There is limited data to support administration of an additional 5 g of PRAXBIND *[see Warnings and Precautions (5.2)]*.

2.2 Preparation

- Ensure aseptic handling when preparing the infusion.