INSTRUCTION FOR USE

PRAXBIND—One recommended dose for all PRADAXA® patients

Dosage

- Recommended dose of 5 g provided as 2 separate vials, each containing 2.5g/50 mL idarucizumab
  - There are limited data to support administration of an additional 5 g of PRAXBIND

FOR INTRAVENOUS USE ONLY

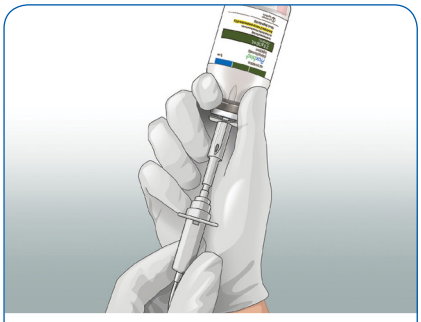
Preparation

- Ensure aseptic handling when preparing and administering the infusion
- Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit
- Once solution has been removed from the vial, administration should begin promptly

Administration

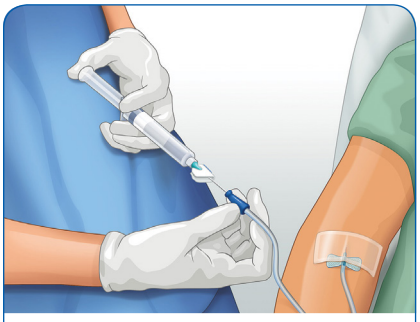
- Do not mix with other medicinal products
- A pre-existing intravenous line may be used for administration of PRAXBIND. The line must be flushed with 0.9% Sodium Chloride Injection, USP solution prior to infusion
- No other infusion should be administered in parallel via the same intravenous access

Option 1: Infusion



Hang vials and administer as 2 consecutive infusions.

Option 2: Bolus Injection



Inject both vials consecutively via syringe.

PRAXBIND treatment can be used in conjunction with standard supportive measures, which should be considered as medically appropriate

- Patients being treated with PRADAXA have underlying disease states that predispose them to thromboembolic events. Reversing PRADAXA 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
- PRAXBIND is a specific reversal agent for PRADAXA, with no impact on the effect of other anticoagulant or antithrombotic therapies
- PRADAXA can be reinitiated 24 hours after administration of PRAXBIND

SELECT SAFETY INFORMATION
WARNINGS AND PRECAUTIONS
Thromboembolic Risk

- Dabigatran-treated patients have underlying diseases predisposing them to thromboembolic events. Reversing dabigatran therapy exposes patients to thrombotic risk. Consider resumption of anticoagulant therapy as soon as medically appropriate.

For more information, please visit www.praxbind.com/dosing-administration

Please see Storage and Handling information on next page.

Please see Indications and Usage and additional Important Safety Information on next page, and full Prescribing Information.

Praxbind® idarucizumab IV INJECTION 5g

Storage and Handling

- Store PRAXBIND vials in the refrigerator at 2ºC to 8ºC (36ºF to 46ºF) in the original carton to protect from light. Do not freeze. Do not shake
- PRAXBIND vials may be stored at room temperature 25°C (77°F) for up to 48 hours if stored in the original package in order to protect from light, or up to 6 hours when out of the carton and exposed to light
- PRAXBIND is a sterile, preservative-free, colorless to slightly yellow, clear to slightly opalescent solution supplied as 2 single-dose vials, each containing 2.5 g/50 mL of idarucizumab

SELECT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

Re-elevation of Coagulation Parameters

- Elevated coagulation parameters (eg, activated partial thromboplastin time or ecarin clotting time) have been observed in a limited number of PRAXBIND-treated patients. If reappearance of clinically relevant bleeding together with elevated coagulation parameters is observed, or if patients requiring a second emergency surgery/urgent procedure have elevated coagulation parameters, an additional full dose may be considered.

Hypersensitivity Reactions

- There is insufficient clinical experience evaluating risk of hypersensitivity to idarucizumab, but a possible relationship could not be excluded. Risk of hypersensitivity (eg, anaphylactoid reaction) to idarucizumab or excipients needs to be weighed cautiously against the potential benefit. If serious allergic reaction occurs, immediately discontinue PRAXBIND and institute appropriate treatment.

Risk in Patients With Hereditary Fructose Intolerance

- PRAXBIND contains 4 g sorbitol as an excipient. When prescribing PRAXBIND in patients with hereditary fructose intolerance, consider the total daily amount of sorbitol/fructose consumption from all sources, as serious adverse reactions (eg, hypoglycemia, hypophosphatemia, metabolic acidosis, increase in uric acid, acute liver failure, and death) may occur.

ADVERSE REACTIONS

- The most frequently reported adverse reaction in ≥5% of idarucizumab-treated healthy volunteers was headache (5%). The most frequently reported adverse reactions in ≥5% of patients were constipation (7%) and nausea (5%).
- Treatment-emergent antibodies with low titers were observed in 4% of healthy subjects and 2% of patients treated with idarucizumab.

USE IN SPECIFIC POPULATIONS

Pregnancy and Lactation

- PRAXBIND should be given to a pregnant woman only if clearly needed. Caution should be exercised when PRAXBIND is administered to a nursing woman.

INDICATIONS AND USAGE

Praxbind® (idarucizumab) 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

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Please see additional Important Safety Information on previous page and accompanying full Prescribing Information.

Boehringer Ingelheim

Praxbind® idarucizumab IV INJECTION 5g