PRAXBIND—One recommended dose for all PRADAXA® patients

Dosage

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

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.

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.
SELECT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont’d)

Elevation of Coagulation Parameters

- Elevated coagulation parameters (e.g., 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 (e.g., 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 (e.g., 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

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