Generic Name:
Idarucizumab
Trade Name:
Praxbind
Company:
Boehringer Ingelheim
Notes:

FDA has expanded the approval of idarucizumab as an antidote to the anticoagulant dabigatran in patients requiring emergency surgery or urgent procedures or who face life-threatening or uncontrolled bleeding.

It is the first of its kind for a reversal agent of a novel oral anticoagulant.

Approval of idarucizumab as a reversal agent was based on data from the RE-VERSE Ad Phase III trial of dabigatran, which was conducted in October 2015. In the trial, 503 patients worldwide at 173 sites were split into two groups: group A (n = 301), in which 60% presented with uncontrolled or life-threatening bleeding, and group B (n = 202), in which 40% required an invasive procedure or an emergency surgery or intervention.

The final results of the trial, published in July 2017, revealed that in 90 patients who received idarucizumab (group A, 51 patients; group B, 39 patients), the median maximum percentage reversal was 100% (95% CI 100-100). According to the researchers, test results were normalized within minutes in 88% to 98% of patients, as measured by ecarin clotting time (82%) or diluted thrombin time (99%).

After 24 hours, concentrations of unbound dabigatran were below 20 mg/mL in 79% of patients. In group A, 35 patients could be assessed for hemostasis, which was restored at a mean of 11.4 hours. In group B, of the 36 patients who underwent a procedure, 33 reported intraoperative hemostasis, and 3 patients reported mildly or moderately abnormal hemostasis.

Only one thrombotic event occurred within 72 hours after idarucizumab was administered to a patient who was not reinitiated to anticoagulants. No adverse safety signals were observed in the study.

Medication Monitor Categories:
Supplemental Approvals