

# Idarucizumab Indications

Idarucizumab is a specific reversal agent for patients with bleeding related to the anticoagulant dabigatran <sup>1)</sup>.

Idarucizumab facilitates the management of patients requiring urgent procedures by providing rapid dabigatran reversal and is the only agent of its class studied in surgical patients <sup>2)</sup>.

Praxbind® is indicated for patients treated with Pradaxa® (dabigatran etexilate), when reversal of the anticoagulant effects of dabigatran is needed for emergency surgery/urgent procedures or in life-threatening or uncontrolled bleeding.

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In the US, Praxbind® is now 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 Regulatory reviews and submissions in other countries are ongoing.4,6 Praxbind® is the only specific reversal agent for a NOAC currently in regulatory review.4 Boehringer Ingelheim plans to submit idarucizumab in all countries where dabigatran is licensed.

About dabigatran etexilate (Pradaxa®) Clinical experience of dabigatran equates to over 4 million patient-years in all licensed indications worldwide. Dabigatran has been in the market for more than 6 years and is approved in over 100 countries.

Currently approved indications for dabigatran are:

Prevention of stroke and systemic embolism in patients with non-valvular atrial fibrillation and a risk factor for stroke Primary prevention of venous thromboembolic events in patients undergoing elective total hip replacement surgery or total knee replacement surgery Treatment of DVT and PE and the prevention of recurrent DVT and recurrent PE in adults Dabigatran, a direct thrombin inhibitor (DTI), was the first widely approved drug in a new generation of direct oral anticoagulants, available to target a high unmet medical need in the prevention and treatment of acute and chronic thromboembolic diseases.

## Idarucizumab in Dabigatran-Treated Patients with Acute Ischemic Stroke Receiving Thrombolytic Therapy

Thrombolytic therapy with recombinant tissue-type plasminogen activator (rt-PA) is used for acute ischemic stroke treatment. Dabigatran is a reversible direct thrombin inhibitor approved for stroke prevention in patients with nonvalvular atrial fibrillation. In such cases, thrombolytic therapy can be administered to certain patients after idarucizumab treatment. Kikule et al. evaluated the effectiveness of idarucizumab in dabigatran-treated patients receiving rt-PA.

They included the data of nine idarucizumab-treated patients from the Riga East University Hospital Stroke Registry from 2018 to 2022 in a retrospective medical records analysis. They used the National Institutes of Health Stroke Scale (LV-NIHSS) score and modified Rankin scale (mRS) on admission and

discharge to evaluate neurological deficit and functional outcomes. Results: We analyzed the data of nine patients (seven males and two females) with a mean age of  $75.67 \pm 8.59$  years. The median door-to-needle time for all patients, including those who received idarucizumab before rt-PA, was 51 min (IQR = 43-133); the median LV-NIHSS score was 9 (IQR = 6.0-16.0) on admission and 4 (IQR = 2.5-4.0) at discharge; and the intrahospital mortality rate was 11.1% due to intracranial hemorrhage as a complication of rt-PA.

The study showed that idarucizumab as an [antidote](#) to [dabigatran](#) appears to be effective and safe in patients with [acute ischemic stroke](#). Furthermore, the administration of idarucizumab slightly prolongs the door-to-needle time; however, the majority of cases showed clinical improvement after receiving therapy. Further randomized controlled trials should be performed to evaluate the safety and effectiveness of idarucizumab for [acute ischemic stroke treatment](#) <sup>3)</sup>.

## Idarucizumab in Dabigatran-Treated Patients with subdural hematoma

[Idarucizumab in Dabigatran-Treated Patients with subdural hematoma.](#)

1)

Eikelboom JW, Quinlan DJ, van Ryn J, Weitz JI. Idarucizumab: The Antidote for Reversal of Dabigatran. *Circulation*. 2015 Dec 22;132(25):2412-22. doi: 10.1161/CIRCULATIONAHA.115.019628. PMID: 26700008.

2)

Levy JH, van Ryn J, Sellke FW, Reilly PA, Elsaesser A, Glund S, Kreuzer J, Weitz JI, Pollack CV Jr. Dabigatran Reversal With Idarucizumab in Patients Requiring Urgent Surgery: A Subanalysis of the REVERSE AD Study. *Ann Surg*. 2019 Oct 9. doi: 10.1097/SLA.0000000000003638. [Epub ahead of print] PubMed PMID: 31599808.

3)

Kikule I, Baborikina A, Haritoncenko I, Karelis G. Idarucizumab in Dabigatran-Treated Patients with Acute Ischemic Stroke Receiving Thrombolytic Therapy. *Medicina (Kaunas)*. 2022 Sep 27;58(10):1355. doi: 10.3390/medicina58101355. PMID: 36295516; PMCID: PMC9607471.

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