



24 September 2015  
EMA/CHMP/575990/2015  
Committee for Medicinal Products for Human Use (CHMP)

## Summary of opinion<sup>1</sup> (initial authorisation)

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### Praxbind

#### idarucizumab

On 24 September 2015, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Praxbind, a specific reversal agent for dabigatran, intended for use when rapid reversal of the anticoagulant effects of Pradaxa (dabigatran etexilate) is required in adult patients.

The applicant for this medicinal product is Boehringer Ingelheim International GmbH.

Praxbind will be available as 2.5g/50 mL solution for injection/infusion. The active substance of Praxbind is idarucizumab, a specific reversal agent for dabigatran (ATC code: V03AB). It is a humanised monoclonal antibody fragment that binds to dabigatran and its metabolites with very high affinity and neutralises their anticoagulant effect. It is used when rapid reversal of dabigatran effect is required.

The benefits with Praxbind are its ability to reverse the anticoagulant effect of dabigatran within 5 minutes of administration, that its action lasts long enough to allow clinical emergency management of patients if needed and that it does not interfere with routine treatment in case of bleeding or urgent surgery.

Mild symptoms suggestive of hypersensitivity have been reported but a causal relationship to idarucizumab could not be established.

The full indication is:

“Praxbind is a specific reversal agent for dabigatran and is indicated in adult patients treated with Pradaxa (dabigatran etexilate) when rapid reversal of its anticoagulant effects is required:

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

It is proposed that Praxbind be restricted to hospital use only.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and

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<sup>1</sup> Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion



made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.