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EPAR summary for the public

Praxbind

idarucizumab

This is a summary of the European public assessment report (EPAR) for Praxbind. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Praxbind.

For practical information about using Praxbind, patients should read the package leaflet or contact their doctor or pharmacist.

What is Praxbind and what is it used for?

Praxbind is a medicine used to neutralise the effects of dabigatran (the active substance of Pradaxa), a medicine that treats and prevents blood clots. Praxbind is used to rapidly stop the anticlotting effect of dabigatran, before emergency surgery or in case of life-threatening bleeding.

Praxbind contains the active substance idarucizumab.

How is Praxbind used?

Praxbind is available as a solution for injection or infusion (drip) into a vein. The recommended dose of Praxbind is 5 g given into a vein as two injections or infusions, one after the other. A second 5-g dose may be given as two further injections or infusions, if needed.

The medicine can only be obtained with a prescription and it is for use in hospital only.

How does Praxbind work?

The active substance in Praxbind, idarucizumab, is a monoclonal antibody fragment. A monoclonal antibody is a type of protein that has been designed to recognise and attach to a specific structure (called an antigen). Praxbind works by attaching firmly to dabigatran, and forming a complex in the blood. This rapidly stops dabigatran's anticlotting effect.

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What benefits of Praxbind have been shown in studies?

Praxbind has been investigated in three main studies involving 141 healthy adults who previously received dabigatran. In the studies, volunteers received either Praxbind or placebo (a dummy treatment) after treatment with Pradaxa for 3.5 days. Results showed that Praxbind was able to completely neutralise Pradaxa's anticlotting effect within 5 minutes of use. In a still ongoing trial, an interim analysis showed similar results in 123 patients who had uncontrolled bleeding or required emergency surgery while using Pradaxa. Most patients in the study were taking Pradaxa to prevent stroke due to an 'abnormal heart beat' (atrial fibrillation).

What are the risks associated with Praxbind?

At the time of authorisation Praxbind has not been associated with any specific side effects.

For the information on the restrictions with Praxbind, see the package leaflet.

Why is Praxbind approved?

The main studies showed that Praxbind is effective at neutralising the effects of Pradaxa, and its action is rapid, complete and sustained. The extent of Praxbind's benefit depends on the patient's overall health, the severity of bleeding and the location of bleeding. No side effects have been identified. The Agency's Committee for Medicinal Products for Human Use (CHMP) therefore decided that Praxbind's benefits are greater than its risks and recommended that it be approved for use in the EU.

What measures are being taken to ensure the safe and effective use of Praxbind?

A risk management plan has been developed to ensure that Praxbind is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Praxbind, including the appropriate precautions to be followed by healthcare professionals and patients.

Further information can be found in the summary of the risk management plan.

Other information about Praxbind

The European Commission granted a marketing authorisation valid throughout the European Union for Praxbind on 20 November 2015.

The full EPAR and risk management plan summary for Praxbind can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Praxbind, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 11-2015.