Praxbind®

319010-02

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Package leaflet: Information for the patient and user

Praxbind®

2.5 g/50 mL solution for injection/infusion

idarucizumab

Read all of this leaflet carefully, because it contains important information for you. Please note this medicine is mainly used in emergency situations and the doctor will have decided that you needed it.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Praxbind is and what it is used for

What Praxbind is

Praxbind contains the active substance idarucizumab. Idarucizumab is a reversal agent specific for dabigatran (Pradaxa), a blood thinner medicine that blocks a substance in the body, which is involved in blood clot formation.

Praxbind is used to rapidly trap dabigatran in order to inactivate its effect.

What Praxbind is used for

Praxbind is used in adults in emergency situations where your doctor decides that rapid inactivation of the effect of Pradaxa is required:
- For emergency surgery/urgent procedures;
- In life-threatening or uncontrolled bleeding.

2. What you need to know when you receive Praxbind

Warnings and precautions

Talk to your doctor or nurse before receiving Praxbind:
- if you are allergic to idarucizumab or to any other of the substances listed in section 6.
- if you have a genetic disease called hereditary fructose intolerance. In this case, the substance sorbitol contained in this medicine may cause serious adverse reactions.

They will take this into account before treating you with Praxbind.

This medicine will only remove dabigatran from your body. It will not remove other medicines used to prevent the formation of blood clots.

After dabigatran has been removed from your body, you are not protected from the formation of blood clots. Your doctor will continue treating you with medicines used to prevent the formation of blood clots as soon as your medical condition allows.

Children and adolescents

There is no information on the use of Praxbind in children.

Other medicines and Praxbind

Tell your doctor if you are taking, have recently taken or might take any other medicines.

This medicine has been designed to only bind to dabigatran. It is unlikely that Praxbind will influence the effect of other medicines or that other medicines will influence Praxbind.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before receiving this medicine.

There is no information on the effects of this medicine in pregnant or breast-feeding women. Praxbind does not affect any functions in the body as such, so your doctor may decide to give you this medicine, if the expected benefits outweigh any potential risks.

Praxbind contains sodium

This medicine contains 50 mg sodium (main component of cooking/table salt) in each dose. This is equivalent to 2.5% of the recommended maximum daily dietary intake of sodium for an adult.

3. How to use Praxbind

This medicine is for hospital use only.

The recommended dose is 5 g (2 vials of 2.5 g/50 mL).

In rare cases you may still have too much dabigatran in your blood after a first dose of this medicine and your doctor may decide to give you a second 5 g dose in specific situations.

Your doctor or nurse will give you this medicine by injection or infusion into a vein.

After you have received this medicine, your doctor will decide on the continuation of your treatment to prevent blood clot formation. Dabigatran can be given again 24 hours after administration of this medicine.

Detailed instructions for your doctor or nurse on how to administer this medicine can be found at the end of this package leaflet (see‘Handling instructions’).

If you have any further questions on the use of this medicine, ask your doctor.

4. Possible side effects

Like all medicines, this medicine may cause side effects, although not everybody gets them.

Until now, no side effects have been identified.

Reporting of side effects

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard
or search for MHRA Yellow Card in the Google Play or Apple App Store

5. How to store Praxbind

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the vial and the carton after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C-8°C).

Do not freeze.

Store in the original package in order to protect from light.

Once opened, this medicine is intended for immediate use.

6. Contents of the pack and other information

What Praxbind contains

- The active substance is idarucizumab.
- The other ingredients are: sodium acetate trihydrate (E262), acetic acid (E260, for pH adjustment), sorbitol (E420), polysorbate 20 (E432) and water for injections.

What Praxbind looks like and contents of the pack

Praxbind is a clear to slightly opalescent, colourless to slightly yellow solution supplied in a glass vial closed with a butyl rubber stopper and an aluminium cap.

Each pack contains two vials.

Marketing Authorisation Holder

Boehringer Ingelheim International GmbH
Binger Str. 173
55216 Ingelheim am Rhein
Germany

Manufacturer

Boehringer Ingelheim Pharma GmbH & Co. KG
Birkendorfer Strasse 65
88397 Biberach an der Riss
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This leaflet was last revised in 02/2023.

The following information is intended for healthcare professionals only:

Praxbind binds specifically to dabigatran and reverses its anticoagulant effect. It will not reverse the effects of other anticoagulants.

Praxbind treatment can be used in conjunction with standard supportive measures, which should be considered as medically appropriate.

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

The recommended dose of Praxbind contains 4 g sorbitol as an excipient. In patients with hereditary fructose intolerance there is a risk for serious adverse reactions, which must be weighed against the benefit of an emergency treatment with Praxbind. If Praxbind is administered in these patients, intensified medical care during Praxbind exposure and within 24 hours of exposure is required.

Dosage and administration:

The recommended dose is 5 g idarucizumab (2 vials of 2.5 g/50 mL).

Administration of a second 5 g dose of idarucizumab may be considered in the following situations:

- recurrence of clinically relevant bleeding together with prolonged clotting times, or
- if potential re-bleeding would be life-threatening and prolonged clotting times are observed, or
- patients require a second emergency surgery/urgent procedure and have prolonged clotting times.

Relevant coagulation parameters are activated partial thromboplastin time (aPTT), diluted thrombin time (dTT) or ecarin clotting time (ECT).

A maximum daily dose has not been investigated.

Praxbind (2 vials of 2.5 g/50 mL) is administered intravenously, as two consecutive infusions over 5 to 10 minutes each or as a bolus injection.

Patients being treated with dabigatran have underlying disease states that predispose them to thromboembolic events. Reversing dabigatran therapy exposes patients to the thrombotic risk of their underlying disease. To reduce this risk, resumption of anticoagulant therapy should be considered as soon as medically appropriate.

Pradaxa (dabigatran etexilate) treatment can be re-initiated 24 hours after administration of idarucizumab, if the patient is clinically stable and adequate haemostasis has been achieved.

After administration of idarucizumab, other antithrombotic therapy (e.g. low-molecular weight heparin) can be started at any time, if the patient is clinically stable and adequate haemostasis has been achieved.

Handling instructions:

Praxbind must not be mixed with other medicinal products. A pre-existing intravenous line may be used for administration of Praxbind. The line must be flushed with sodium chloride 9 mg/ml (0.9%) solution for injection prior to and at the end of infusion. No other infusion should be administered in parallel via the same intravenous access.

Praxbind is for single-use only and does not contain preservatives.

Prior to use, the unopened vial may be kept at room temperature (up to 30°C) for up to 48 hours, if stored in the original package in order to protect from light. After opening the vial, chemical and physical in-use stability of idarucizumab has been demonstrated for 6 hours at room temperature (up to 30°C). The solution should not be exposed to light for more than 6 hours (in unopened vial and/or in-use).

From a microbiological point of view, unless the method of opening precludes the risk of microbial contamination, the product shall be used immediately after opening. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user.

No incompatibilities between Praxbind and polyvinyl chloride, polyethylene or polyurethane infusion sets or polypropylene syringes have been observed.