Praxbind®

Solution for Injection/Infusion

idarucizumab, rch

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Praxbind.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Praxbind against the benefits they expect it will have for you.

If you have any concerns about being treated with this medicine, ask your doctor.

This leaflet was last updated on the date at the end of this leaflet. More recent information may be available. The latest Consumer Medicine Information is available from your pharmacist, doctor, or from www.medsafe.govt.nz/Consumers/cmi/CMIForm.asp and may contain important information about the medicine and its use of which you should be aware.

Keep this leaflet.

You may need to read it again.

What Praxbind is used for

Praxbind contains the active substance idarucizumab and is a reversal agent specific for Pradaxa (dabigatran etexilate), 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.

Praxbind is used in emergency situations where your doctor decides that rapid inactivation of the effect of Pradaxa (dabigatran etexilate) is required such as:

- for emergency surgery/urgent procedures
- in life-threatening or uncontrolled bleeding.

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.

Ask your doctor if you have any questions about why this medicine is being given to you.

Your doctor may have prescribed it for another reason.

Before you are given Praxbind

When you must not be given it

Praxbind must not be used after the expiry date printed on the pack or vial or if the packaging is torn or shows signs of tampering.

If you are not sure whether you should be given this medicine, talk to your doctor.

Before you are given it

Tell your doctor if you:

- are allergic to any medicine containing idarucizumab or any of the ingredients listed at the end of this leaflet. Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body, rash, itching or hives on the skin.
- have a genetic disease called hereditary fructose intolerance. In this case, the substance sorbitol contained in Praxbind may cause serious adverse reactions.
- are on a sodium restricted diet. Praxbind contains 50 mg sodium per dose.

Your doctor will take this into account before treating you with Praxbind.

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.

Your doctor can discuss with you the risks and benefits involved.

If you are uncertain as to whether you have, or have had, any of these

conditions you should raise those concerns with your doctor.

If you have not told your doctor about any of the above, tell him/her before you are given Praxbind.

Children and adolescents

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

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

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

How Praxbind is given

How much is given

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

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

How it is given

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

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

If you are given too much (overdose)

As Praxbind is given to you under the supervision of your doctor, it is very unlikely that you will receive too much.

Side effects

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

Until now, no side effects have been identified.

Tell your doctor or nurse as soon as possible if you experience any side effects during or after treatment with Praxbind, so that these may be properly treated.

Ask your doctor or nurse to answer any questions you may have.

After being given Praxbind

Tell your doctor or nurse immediately if you notice any of the following:

- long or excessive bleeding
- exceptional weakness
- tiredness, headaches, dizziness and looking pale (signs of anaemia)
- chest pain or being short of breath
- red or dark brown urine
- red or black bowel motions.

These are signs or symptoms of bleeding. You may need urgent medical attention.

Storing Praxbind

Praxbind will be stored in the pharmacy or ward in a refrigerator at 2°C to 8°C.

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 to protect from light. The unopened vial may be kept at room temperature for up to 6 hours when exposed to light.

Once the solution has been removed from the vial, Praxbind can be kept at room temperature for up to 6 hours.

Each vial can only be used once and unused contents of opened vials must be discarded.

Product description

What it looks like

Praxbind is a clear to slightly opalescent, colourless to slightly yellow solution. Praxbind is supplied in a 50 mL glass vial, closed with a rubber stopper and secured with an aluminium flip-off cap.

Praxbind is available in packs of 2 vials.

Ingredients

Each 50 mL vial of Praxbind contains 2.5 g of idarucizumab. It also contains glacial acetic acid, polysorbate 20, sodium acetate trihydrate, sorbitol and water for injection.

Supplier

Praxbind is supplied in New Zealand by:

Boehringer Ingelheim (N.Z.) Limited

Auckland

This Consumer Medicine Information was updated in August 2017.