

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I being given Praxbind?

Praxbind contains the active ingredient idarucizumab, which is a reversal agent specific for Pradaxa (dabigatran etexilate), a blood thinner medicine that helps prevent blood clots. Praxbind is used to rapidly trap dabigatran in order to inactivate its effect.

For more information, see Section [1. Why am I being given Praxbind?](#) in the full CMI.

2. What should I know before I am given Praxbind?

Do not use if you have ever had an allergic reaction to idarucizumab or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I am given Praxbind?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Praxbind and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How will I be given Praxbind?

A doctor or nurse will give you Praxbind by injection or infusion into a vein. It is not for self-administration.

More instructions can be found in Section [4. How will I be given Praxbind?](#) in the full CMI.

5. What should I know after being given Praxbind?

Things you should do	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.
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For more information, see Section [5. What should I know after being given Praxbind?](#) in the full CMI.

6. Are there any side effects?

Tell your doctor or nurse if you notice any of the following and they worry you: headache, back pain, fever, wheezing, rash and itchy skin.

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.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Praxbind®

Active ingredient(s): *idarucizumab*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Praxbind. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about being given Praxbind.**

Where to find information in this leaflet:

- [1. Why am I being given Praxbind?](#)
- [2. What should I know before I am given Praxbind?](#)
- [3. What if I am taking other medicines?](#)
- [4. How will I be given Praxbind?](#)
- [5. What should I know after being given Praxbind?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I being given Praxbind?

Praxbind contains the active ingredient idarucizumab.

Praxbind 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.

2. What should I know before I am given Praxbind?

Warnings

You must not be given Praxbind if:

- You are allergic to idarucizumab, or any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can use this medicine.

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

Check with your doctor if you:

- have allergies to any other medicines, foods, preservatives or dyes
- have any other medical conditions
- take any medicines for any other condition
- 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.

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.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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

Children and adolescents

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

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy 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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Praxbind.

4. How will I be given Praxbind?

How much Praxbind will I be 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 is Praxbind 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 24 hours after Praxbind administration.

If you are given too much Praxbind

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

5. What should I know after being given Praxbind?

Things you should do

Call your doctor straight away 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.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Side effects

Side effects	What to do
Signs of an allergic reaction • 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	Tell your doctor or nurse as soon as possible if you experience any side effects during or after treatment with

Side effects	What to do
Other side effects: • headache • back pain • fever	Praxbind, so that these may be properly treated.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Praxbind contains

Active ingredient (main ingredient)	Each 50 mL vial of Praxbind contains 2.5 g of idarucizumab
Other ingredients (inactive ingredients)	• glacial acetic acid • polysorbate 20 • sodium acetate trihydrate • sorbitol • water for injections

Do not take this medicine if you are allergic to any of these ingredients.

What Praxbind looks like

Praxbind (AUST R 237761) 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.

Who distributes Praxbind

Praxbind is supplied in Australia by:

Boehringer Ingelheim Pty Limited

ABN 52 000 452 308

Sydney NSW

www.boehringer-ingelheim.com.au

* Praxbind is a registered trade mark of Boehringer Ingelheim.

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