READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

[Pr]PRAXBIND®
(Prăcks-bīnd)

Idarucizumab Solution for Injection

Read this carefully before you start taking **PRAXBIND** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **PRAXBIND**.

What is PRAXBIND used for?
PRAXBIND should only be given to adult patients who are taking a blood-thinning drug called Pradaxa® (dabigatran etexilate).

PRAXBIND is used in emergency situations where a doctor decides that rapid reversal of the effect of Pradaxa® is required:

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

How does PRAXBIND work?
PRAXBIND contains idarucizumab, which is a special type of protein called a monoclonal antibody.

PRAXBIND must be administered into your vein by your healthcare provider in order to work. Once in your bloodstream, PRAXBIND immediately and tightly binds to Pradaxa®, reversing its anti-clotting effect. The PRAXBIND - Pradaxa® complex is then removed via your kidneys.

What are the ingredients in PRAXBIND?
Medicinal ingredient: idarucizumab

Non-medicinal ingredients: acetic acid glacial, polysorbate 20, sodium acetate trihydrate, sorbitol, water for injection

PRAXBIND comes in the following dosage forms:
PRAXBIND is supplied as a sterile solution for injection into your vein and is administered in two 50 mL vials, each containing 2.5 g of idarucizumab. Two vials equal one dose.

Do not use PRAXBIND if:
- You are allergic (hypersensitive) to idarucizumab or to any of the other non-medicinal ingredients of PRAXBIND (see section "**What are the ingredients in PRAXBIND**" above).

To help avoid side effects and ensure proper use, talk to your healthcare professional

before you take PRAXBIND. Talk about any health conditions or problems you may have, including if you:

- Have a genetic disease called hereditary fructose intolerance or allergy to sorbitol as the sorbitol contained in this medicine may cause serious adverse reactions.

Other warnings you should know about:
PRAXBIND will only work for reversal of Pradaxa®. It will not reverse other medicines used to prevent the formation of blood clots.

Tell your healthcare professional about all the medicines you take, including any prescription or non-prescription drugs, vitamins, minerals, natural supplements or alternative medicines.

Preclinical studies have shown no interactions of PRAXBIND with volume expanders, coagulation factor concentrates and anticoagulants other than Pradaxa®.

Based on the properties and the high specificity in binding to dabigatran, clinically relevant interactions with other medicinal products are considered unlikely.

Pregnancy
There is no information about the use of PRAXBIND in pregnant women. Tell your doctor if you are pregnant or planning to become pregnant (*planning to have a baby*). The doctor will weigh the benefits against the risks of taking PRAXBIND while you're pregnant.

Breast-feeding
It is not known whether the ingredients of PRAXBIND can pass into human milk. If you are breast-feeding, tell the doctor.

How PRAXBIND is administered:
PRAXBIND must be administered into your vein by your healthcare provider. PRAXBIND will be prepared in a hospital as an infusion (a drip) over several minutes or an injection (with a syringe).

Usual Dose:
The usual dose of PRAXBIND is 5 g which is supplied as two 50 mL vials of 2.5 g each. Two vials is equivalent to one dose.

Overdose:
There is no clinical experience with overdoses of PRAXBIND.

What are possible side effects from using PRAXBIND?

If you experience any side effects such as hypersensitivity or allergic reaction symptoms, after PRAXBIND administration, inform your healthcare professional.

If you have a troublesome symptom or side effect after PRAXBIND administration which becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

In studies of very sick patients, worsening of ongoing conditions such as shock, organ failure or bleeding into the brain have occurred. These are not related to treatment with PRAXBIND. Treatment methods may include administration of fluids, blood transfusion or even surgery.

Symptoms of anaphylactic shock (sudden drop in blood pressure) and other potential hypersensitivity (fever, difficulty in breathing or wheezing, increased frequency of rapid breathing, rash or itching) were also reported in patients. Adverse events reported in greater than or equal to 5% of patients were difficulty passing stools (7%). These were reported in a clinical trial, but may not be directly related to PRAXBIND.

After treatment with PRAXBIND, a temporary excess of protein in the urine has been observed.

Stopping treatment with the blood-thinning drug Pradaxa®, may lead to increased risk of a blood clot in major blood vessels in your lungs or heart. This could potentially lead to a heart attack or stroke. You may need to resume treatment with drugs which dissolve the blood clots as soon as medically appropriate.

Possible side effects* and what to do about them		
Symptom / effect	Talk to your healthcare professional	
	Only if severe	In all cases
Hypersensitivity:		
Fever	✓	
Difficulty in breathing or wheezing		✓
Increased frequency of rapid breathing		✓
Rash	✓	
Itching	✓	

* These were reported in a clinical trial, but may not be directly related to PRAXBIND.

Re-administration of Pradaxa® (dabigatran etexilate)
24 hours after administering PRAXBIND, re-administration of Pradaxa® may be considered by your doctor.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:
PRAXBIND will be stored at 2-8°C in a hospital.

If you want more information about PRAXBIND:
- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html), the manufacturer's website (http://www.boehringer-ingelheim.ca), or by calling the manufacturer, Boehringer Ingelheim (Canada) Ltd., at: 1-800-263-5103, extension 84633.

This leaflet was prepared by Boehringer Ingelheim (Canada) Ltd. The information in this leaflet is current up to the time of the last revision date shown below, but more current information may be available from the manufacturer.

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