PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

Praxbind®

Boehringer Ingelheim

Solution for infusion

Idarucizumab 50 mg/mL

Sugar Free

Read all of this leaflet carefully before you are given PRAXBIND

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.

What is in this leaflet

6. Contents of the pack and other information

1. What PRAXBIND is and what it is used for

Praxbind is used in emergency situations where your health care provider decides that rapid inactivation of the effect of a medicine called dabigatran is required:

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

2. What you need to know before you receive PRAXBIND

Warnings and precautions

Tell your health care provider before being given the infusion

- If you are allergic to idarucizumab or to any of the inactive ingredients in PRAXBIND solution for infusion.

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

- Always tell your health care provider if you are taking any other medicine (this includes complementary or traditional medicines).
- 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.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before receiving this medicine.

Driving and using machines

Not applicable.

Important information about some of the ingredients of PRAXBIND

Sorbitol

If you have a genetic disease called hereditary fructose intolerance, the substance sorbitol contained in this medicine may cause serious adverse reactions.

Sodium

PRAXBIND contains 50 mg sodium (main component of cooking/table salt) in each dose. You should tell your healthcare provider if you are on a sodium controlled diet.

3. How to receive PRAXBIND

PRAXBIND is given by injecting or infusing 5 g (two vials of 50 mL of solution) into a vein.

You will not be expected to give yourself PRAXBIND. It will be given to you by a person who is qualified to do so.

Detailed instructions for your health care provider on how to administer PRAXBIND can be found in the professional information which accompanies this patient information leaflet (see section 6.6 in the professional information).

After you have received PRAXBIND, your health care provider will decide on the continuation of your treatment to prevent blood clot formation. Dabigatran can be given again after 24 hours.

If you receive more PRAXBIND than you should

Since a health care provider will administer this medicine, he/she will control the dosage. However, in the event of overdosage your health care provider will manage the overdosage.

4. Possible side effects

PRAXBIND can have side effects.

Up to now, no side effects have been identified.

Should your general health worsen or if you experience any untoward effects while receiving PRAXBIND, please consult your healthcare provider for advice.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety App (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website.
Suspected adverse reactions can also be reported directly to the holder of the certificate of registration using the email address pv_local_south_africa@boehringer-ingelheim.com.
By reporting side effects, you can help provide more information on the safety of PRAXBIND.

5. How to store PRAXBIND

Store in a refrigerator (2 – 8 ˚C). Do not freeze. Keep the containers in the outer carton in order to protect from light.
PRAXBIND may be exposed to conditions at or below 25 ˚C for a maximum period of 3 months during transportation and handling.

Store all medicines out of the reach of children**.**

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

Do not use PRAXBIND if you notice particles or discolouration prior to administration.

Once opened, PRAXBIND is intended for immediate use.

For in-use storage instructions refer to section 6.3 in the professional information which accompanies this patient information leaflet.

Return all unused or expired medicines to your health care provider for safe disposal. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What PRAXBIND contains

The active substance is idarucizumab. One vial of 50 mL contains 2,5 g idarucizumab.

The other (inactive) ingredients are polysorbate 20, sodium acetate trihydrate, sorbitol and water for injection.

Contains 2 g of sorbitol and 25 mg sodium per vial – see section 2.

What PRAXBIND looks like and contents of the pack

PRAXBIND is a clear to slightly opalescent, colourless to slightly yellow solution, essentially free from foreign particles, but may contain a few translucent, white to whitish product typical particles.

Each pack contains two clear, colourless 50 mL glass vials with grey rubber stoppers and secured with blue aluminium flip-off caps, each bearing a label with integrated hanger, packed in a printed cardboard carton with the professional information and patient information leaflet.

Holder of Certificate of Registration

Ingelheim Pharmaceuticals (Pty) Ltd

Suite 1, Building 4, 2nd Floor

Waterfall Corporate Campus

74 Waterfall Drive

Midrand

South Africa

Tel No.: +27 (011) 348-2400

This leaflet was last revised in

23 May 2025

Registration number

50/30.1/0315