IDARUCIZUMAB (PRAXBIND®)

Reversing effects of DABIGATRAN (Pradaxa®)

This information sheet provides a summary of use of IDARUCIZUMAB. This information should be used in conjunction with Therapeutic Goods Administration (TGA) approved Product Information (PI), Clinical Excellence Commission (CEC) Non-Vitamin K Antagonist Oral Anticoagulant (NOAC) Guidelines and specialist advice.

IDARUCIZUMAB is a specific reversal agent for dabigatran. IDARUCIZUMAB **cannot** be used to reverse the effects of factor Xa inhibitors such as apixaban (Eliquis®) or rivaroxaban (Xarelto®).

Availability

IDARUCIZUMAB may not be available in all facilities. Clinicians should verify availability with their relevant Drug and Therapeutics Committee and Pharmacy Department.

Indications

IDARUCIZUMAB is indicated when rapid reversal of the anticoagulant effects of dabigatran is required for:

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

In mild or moderate bleeding e.g. patients presenting with a non-life threatening bleed or in need of non-urgent surgery or invasive procedure, discontinuation of dabigatran and administration of appropriate supportive care is usually sufficient.

Action

IDARUCIZUMAB completely reverses the anticoagulant effect of dabigatran within minutes. Achieving haemostasis however, may take several hours and will be dependent on identifying and treating the source of bleeding.

Drug interactions

No formal interaction studies with IDARUCIZUMAB and other medicines have been conducted. Clinically relevant interactions with other medicines are considered unlikely.

References:

Boehringer Ingelheim Pty Limited. Product Information Praxbind® (idarucizumab). Therapeutic Goods Administration Website 2015 [May 2016]; Available from: www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2016-PI-01849-1.

Pollack CV, Reilly PA, Eikelboom J, Glund S, Verhamme P, Bernstein RA, et al. Idarucizumab for dabigatran reversal New England Journal of Medicine. 2015;373 (6):511-20.

Therapeutic Goods Administration. Public Summary PRAXBIND idarucizumab. In: Australian Register of Therapeutic Goods, editor: Commonwealth of Australia; 2016.

Dosage and administration

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

Administered intravenously, as two consecutive infusions over 5 to 10 minutes each or as a bolus injection

No dose adjustment is required for renal impairment.

Image: Boehringer Ingelheim
Image not to scale

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
- Patient requires a second emergency surgery/urgent procedure and has prolonged clotting times (see Monitoring).

The safety and efficacy of repeat treatment with IDARUCIZUMAB have not been established.

Monitoring

Conduct the following, before IDARUCIZUMAB administration and 30 minutes after IDARUCIZUMAB administration:

- aPTT
- PT
- Fibrinogen
- TT (thrombin clotting time).

IDARUCIZUMAB is only indicated if the TT is prolonged. A normal TT rules out the presence of dabigatran.

The TT is extremely sensitive, even to clinically insignificant levels of dabigatran. Repeat doses of IDARUCIZUMAB should not be based on repeat TT results in isolation.

Restarting dabigatran

Reversing dabigatran exposes patients to the thrombotic risk of their underlying disease. Resumption of anticoagulant therapy should be considered as soon as medically appropriate. Specialist advice should be sought. Dependent on patient circumstances, treatment can be initiated 24 hours after administration of IDARUCIZUMAB (refer to CEC NOAC Guidelines).

Idarucizumab (Pradbind®) Reversing effects of dabigatran (Pradaxa®) Released August 2016.