Idarucizumab Intravenous for Adults

Who can administer

May be administered by registered competent doctor or nurse/midwife

Important information

- **Consultant approval required as high cost drug**
- This is not a blood product, and **does not require** Consultant Haematologist approval
- **Supply available in pharmacy: Fridge 2, Shelf 10, UCHG**
- Idarucizumab binds specifically to dabigatran and reverses its anticoagulant effect. **It will not reverse the effects of other anticoagulants**
- In order to improve the traceability of biological medicinal products, **the name and batch number of the administered product should be clearly recorded**
- Precautions need to be taken during administration to **prevent possible air embolism** - particularly in central line administration. Bottles must be vented in one of two ways: directly by means of a filter needle into the bottle which goes through the rubber stopper and opens into the air, or direct air vent on the air inlet of the administration set, located between the drip chamber and piercing pin, it is covered with a bacterial retentive filter to reduce the chance of contamination

Available preparations

Praxbind 2.5g per 50ml vial

Reconstitution

Already in solution

Infusion fluids

Not required- product ready for infusion

Methods of intravenous administration

Gloves, protective eyewear and a mask should ideally be worn by those handling this drug (ref 2)

Intermittent intravenous infusion (preferred method)

- Administer a 5g dose as two consecutive infusions of 2.5g per 50ml over 5 to 10 minutes each
- The residual volume in the infusion line must be flushed through at the same rate to avoid

significant underdosing

Bolus intravenous injection - see under further information

Dose in adults

Usual dose

- Give 5g (as two bottles of 2.5g administered one immediately after another)

Repeat doses

- A **second dose of 5g is unlikely to be required and must always be discussed with Haematology**
- 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
    - if potential re-bleeding would be life-threatening and prolonged clotting times are observed, or
    - patients require a second emergency surgery/urgent procedure and have prolonged clotting times.
- Dabigatran causes prolongation of the activated Partial Thromboplastin Time (aPTT) and Thrombin time (TT)
- **The presence of a normal thrombin time excludes the presence of dabigatran**. Patients who are bleeding may develop coagulopathies for other reasons other than the presence of the drug, and this should be borne in mind if repeat administration is being considered [(ref 1)]

Renal or hepatic impairment

- No dosage adjustment is required

Monitoring

- Relevant coagulation parameters are activated Partial Thromboplastin Time (aPTT) and Thrombin time (TT)
- Additional testing as per Haematology (ref 1)

Further information

- The manufacturers suggest that **the drug may be given as a bolus injection** (as an alternative to a short infusion) - however, we feel that the infusion method is preferable due to the volume (100ml per dose) involved.
- **Reversal effects are usually evident immediately** after administration (plasma concentrations of unbound dabigatran reduced by more than 99%)
- **The majority of patients (>90%) showed sustained reversal of dabigatran plasma concentrations**
    - In a subset of patients, **recurrence of plasma levels of unbound dabigatran** and concomitant elevation of clotting times was observed, possibly due to redistribution of dabigatran from the periphery
    - This occurred **1 to 24 hours after administration of idarucizumab** mainly at time points of 12 hours or more

- **Dabigatran can be re-initiated** 24 hours after administration of idarucizumab, if the patient is clinically stable and adequate haemostasis has been achieved
- After administration of idarucizumab, other anti-thrombotic therapy (e.g.LMWH) can be started at any time, if the patient is clinically stable and adequate haemostasis has been achieved

Storage

- Store between 2 and 8^{0}C
- Do not freeze
- Prior to use, the unopened vial may be kept at room temperature (up to 30^{0}C) for up to 48 hours, if stored in the original package in order to protect from light

References

SPC Jan 2025

1: Specialist opinion Dr Ruth Gilmore, Consultant Haematologist, GUH 26/03/2025

2:Clinical Oncology Society of Australia. Position statement: safe handling of monoclonal antibodies in healthcare settings 2022 update

Therapeutic classification

Reversal agent for dabigatran ONLY (monoclonal antibody fragment)