SESLHD MG/110

Medicine Guideline

Idarucizumab in Urgent Dabigatran Reversal

Areas where Protocol/Guideline applicable	SESLHD Inpatients with supervision of a clinical haematologist
Authorised Prescribers:	Consultant haematologists only
Indication for use	Patient requiring immediate urgent reversal of anticoagulation by dabigatran
Clinical condition Patient selection: Inclusion criteria (list investigations necessary and relevant results)	Patients therapeutically anticoagulated with dabigatran who require immediate reversal for life-saving surgical or invasive procedures which cannot be performed whilst therapeutically anticoagulated or who are suffering from life-threatening bleeding.
Proposed Place in Therapy	First line in consultation with Haematologist. Idarucizumab can be used in conjunction with standard supportive measures. These may include mechanical compression, surgical repair of the bleeding site, fluid replacement, packed red cell transfusion and fresh frozen plasma (FFP) or platelet transfusion if clinically indicated. The concomitant use of coagulation factors such as Beriplex P/N® may also be considered at the judgement of the treating physician
Contra-indications	• Hypersensitivity to idarucizumab (subjects with hereditary fructose intolerance may react to sorbitol) • Minor bleeding which can be managed with supportive care • Surgery or procedure is elective
Precautions	Thromboembolic disease
Important Drug Interactions	Nil No incompatibilities between idarucizumab and polyvinyl chloride, polyethylene or polyurethane infusion sets or polypropylene syringes have been observed.
Dosage	Total dose is 5 g (using 2 x 2.5 g in 50 mL vials, 50 mg/mL). No dose adjustment is required in renally impaired patients and in patients with hepatic impairment.
Duration of therapy	Single treatment (of two consecutive vials no more than 15 minutes apart).

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Health
South Eastern Sydney
Local Health District

Prescribing Instructions	Idarucizumab must be prescribed on the eMR or eRIC. In the absence of eMM systems, the appropriate paper medication chart may be used.
Administration Instructions	Idarucizumab must not be mixed with other medicines. The intravenous line must be flushed with sodium chloride 0.9% prior to and at the end of the infusion. Infuse each 2.5 g in 50 mL vial intravenously over 5 to 10 minutes as consecutive doses or the two 2.5 g doses may be given as separate bolus injections as quickly as possible. The total dose is 5 g (2 x 2.5 g in 50 mL infusions)
Monitoring requirements Safety Effectiveness (state objective criteria)	Clinical parameters e.g. bleeding Following dosage and the following day, the coagulation parameters, APTT, TT and dabigatran level should be checked to ensure that the dabigatran has been fully reversed. A small number of people especially those with renal failure may have a rebound of the dabigatran level and if there is any ongoing bleeding then consideration of further dosing in consultation with the supervising haematologist may be required.
Storage	Store in a monitored refrigerator at 2°C to 8°C. Do not freeze. Store in the original package. Protect from light. The unopened vial may be kept at room temperature (25°C) for; • up to 48 hours if stored in the original package (protected from light) • up to 6 hours when exposed to light
Storage Location **(Only for release with haematologist approval)**	**Prince of Wales Hospital**: Blood Bank **St. George Hospital**: Blood Bank **Sutherland Hospital**: Blood Bank
Management of Complications	Treat symptomatically
Basis of Protocol/Guideline: (including sources of evidence, references)	Pollack CV, Reilly PA, Eikelboom J et al. Idarucizumab for Dabigatran Reversal N Engl J Med 2015;373:511-520 Glund S, et al. Safety, tolerability and efficacy of Idarucizumab for the reversal of the anticoagulant effect of dabigatran in healthy male volunteers. Lancet 2015 Idarucizumab (Praxbind®) Product Information via CIAP. Last updated 14 January 2022.
Groups consulted in development of this guideline	Haematologists, POWH and SGH

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GOVERNANCE	
Enactment date *Reviewed* (Version 2) *Reviewed* (Version 3)	March 2016 September 2021 October 2024
Expiry date:	31 October 2027
Ratification date by SESLHD DTC Committee	3 October 2024
Chairperson, DTC Committee	Dr John Shephard
Version Number	3