Prescribing Protocol SESLHDPR/571

Idarucizumab in Urgent Dabigatran Reversal

Areas where applicable	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	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.		
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	Recurrent thromboembolic disease		
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 Prothrombinex® may also be considered at the judgement of the treating physician		
Dosage	Total dose is 5 g (using 2 x 2.5 g in 50 mL vials, 50 mg/mL). Infuse each vial intravenously over 5 to 10 minutes.		
Duration of therapy	Single treatment (of two consecutive vials no more than 15 minutes apart).		
Important Drug Interactions	Nil No incompatibilities between idarucizumab and polyvinyl chloride, polyethylene or polyurethane infusion sets or polypropylene syringes have been observed.		
Storage	Store in a monitored refrigerator at 2°C to 8°C. Do not freeze. Store in the original package. Protect from light. Shelf life 30 months.		
Storage Location **(Only for release with haematologist approval)**	**Prince of Wales Hospital**	**St. George Hospital**	**Sutherland Hospital**
	Blood Bank	Blood Bank	Blood Bank
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	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.
Management of complications	Treat symptomatically
Basis of Protocol/Guideline:	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
Groups consulted in development of this guideline	POWH Drug and Therapeutics Committee Haematologists, POWH and SGH

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GOVERNANCE	
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