TRANSFUSION MEDICINE PROTOCOLS

Factor IX (9)

This document should be read in conjunction with the Disclaimer

Discuss all requests for Factor IX with the Consultant Haematologist.

PREPARATIONS	Plasma-derived Factor IX	Recombinant Factor IX
FORMULATIONS	**MonoFIX®-VF** MonoFIX®-VF Product Information MonoFIX®-VF is presented in two different concentrations (strengths): 50 IU/mL and 100 IU/mL.	**BeneFIX®** BeneFIX® Product Information
SPECIFICATIONS	MonoFIX®-VF 500 IU vial (50 IU Factor IX/mL) contains 500 IU Factor IX and 1.25 IU Anti-Thrombin III. Manufactured from pooled human plasma.	Coagulation Factor IX, recombinant.
VIAL SIZE	500 and 1000 IU	250, 500, 1000 and 2000 IU
INDICATIONS	Treatment and prophylaxis in patients with haemophilia B. **Note:** However the 1st choice product is usually recombinant Factor IX. (BeneFIX®) Treatment of haemorrhage for use in surgery	Recombinant Factor IX is the treatment of choice for patients with Haemophilia B.

PRODUCT	Plasma-derived Factor IX	Recombinant Factor IX
CONTRAINDICATIONS AND PRECAUTIONS	MonoFIX®-VF should be used with caution in patients with a previous or known severe allergy to Factor IX concentrates. High doses of prothrombin complex concentrates been associated with disseminated intravascular coagulation (DIC). Although MonoFIX®-VF contains purified Factor IX, the potential risk of thrombosis and DIC should be recognised. The use of products containing Factor IX could be hazardous in patients with a history of fibrinolysis, myocardial infarction, DIC or liver disease.	BeneFIX® is contraindicated in patients who have manifested life-threatening, immediate hypersensitivity reactions, including anaphylaxis, to the product or components, including hamster protein. **WARNING AND PRECAUTIONS** Anaphylaxis and severe hypersensitivity reactions are possible. Should symptoms occur, treatment with the product should be discontinued, and emergency treatment should be sought. Patients may develop hypersensitivity to hamster (CHO) protein as BeneFIX® contains trace amounts. BeneFIX® has been associated with the development of thromboembolic complications, including patients receiving continuous infusion through a central venous catheter. Nephrotic syndrome has been reported following immune tolerance induction with Factor IX products in haemophilia B patients with Factor IX inhibitors and a history of allergic reactions to Factor IX
CONSUMER INFORMATION	MonoFIX® Consumer Medicine Information	BeneFIX® Consumer Medicine Information

PRODUCT	Plasma-derived Factor IX	Recombinant Factor IX
CONSENT	Manufactured from pooled human plasma. Written consent required. Refer to WNHS Blood Product Consent and Refusal	This is not a blood product. Document consent for treatment.
DOSE	Requests and dosage of all Factor IX products must be discussed with the Consultant Haematologist.	
ORDERING	Ordered on a named patient basis from Transfusion Medicine Unit (TMU).	
RECONSITUTION	⚠CAUTION For instructions on reconstitution/filtration, refer to the individual product information and other supporting material accompanying the product. MonoFIX®-VF Reconstitution Guide BeneFIX® Reconstitution Guide For information on using the Mix2Vial™ Mix2Vial™	
ADMINISTRATION	• Two staff to perform checks as per the Clinical Practice Manual, WNHS Pharmacy Medication Checking and Administration processes. Check Issue label and patient ID. Check right patient, right product, right dose – prescription matches product supplied. If not identical, contact TMU and prescribing doctor. • Verify that the prescription is complete, including clearly stating the type of Factor IX. • Administered IV –as a bolus dose. • Bolus dose administration – refer to individual product information for appropriate rate as specified by prescribing medical officer. • Do not mix/piggy back this product with other medications or IV fluids/blood products.	
OBSERVATIONS	⚠WARNING **Patients with Factor IX inhibitors may be at an increased risk of anaphylaxis upon subsequent challenge with Factor IX. Patients should be observed closely for signs and symptoms of acute hypersensitivity reactions, particularly during the early phases of initial exposure to product.** • Must be administered under constant visual observation. • Vital signs (temperature, pulse, respiration, blood pressure) must be undertaken and recorded on the observation chart in the medical	

	notes. Observe for signs of any adverse reaction. • Monitor patient for at least 10 minutes post administration.
ADVERSE REACTIONS	Symptoms may include: skin rash, itching, tightness of throat or chest, shortness of breath, chest pain or wheezing. High doses have been associated with disseminated intravascular coagulopathy. For more information refer to the Product Information: • BeneFIX® Product Information • MonoFIX®-VF Product Information Adverse reaction should be reported to the Clinical Haematologist and TMU. Refer to WNHS Management of Transfusion Reactions and Adverse Events, as a guide to patient treatment and management.
DOCUMENTATION	A record must be kept in the patient's medical notes of the following • The date and time of administration • Amount given • The batch number and expiry date of each bottle used must be attached to the Blood Product Administration Record/ Transfusion Record MR735 (product has a peel off label with batch number and expiry date on). This information is important should the patient have a reaction or if there is a need to trace recipients of certain batch numbers at a later date.
For further information, refer to product insert. Return product to TMU immediately if no longer required. Product should be used for intended patient (issue label) only.	

References

- Australian Red Cross Blood Service (ARCBS) – Blood products and transfusion practice for health professionals. Australian Red Cross website
- ARCBS – Blood products and transfusion practice for health professionals. http://www.transfusion.com.au/blood_products/fractionated_plasma/immunoglobulins
- The Australian Blood Service (ARCBS) Blood Component Information http://www.transfusion.com.au/sites/default/files/BCI%202009.pdf
- BeneFIX® Product Information
- MonoFIX®-VF Product Information
- A range of guidelines for use of coagulation factors and management of haemophilia and other bleeding disorders (Australian Haemophilia Centre Directors' Organisation), are available at www.ahcdo.org.au/publications
- National Safety and Quality Health Service Standards, October 2012. Standard 7: Blood and Blood Products

Related WNHS policies, procedures and guidelines

- WNHS Blood Product Prescription, Consent and Refusal
- WNHS Management of Transfusion Reactions and Adverse Events
- WNHS Transfusion Equipment and Administration
- WNHS Pharmacy Medication Checking and Administration
- Neonatology Clinical Care Guidelines
- Obstetrics and Gynaecology Clinical Guidelines
- WNHS Pharmacy Medication Checking and Administration

File path:	WNHS.HAEM.FactorIX(9) Monofix and Benefix		
Keywords:	Blood Transfusion, Blood products, Monofix, Benefix, Factor IX, Factor 9, administration of Factor IX, plasma derived blood products. Haemophilia, Blood bank, transfusion medicine unit, blood bank scientist		
Document owner:	Chair of KEMH Hospital Transfusion Committee		
Author / Reviewer:	Consultant Haematologist, Scientist in Charge Transfusion Medicine, KEMH Transfusion Coordinator		
Date first issued:	01 01 2005		
Last reviewed:	01 10 2017	Next review date:	01 10 2020
Endorsed by:	KEMH Hospital Transfusion Committee	Date:	01 02 2017
Standards Applicable:	NSQHS Standards: 1 Governance, 5 Patient ID/Procedure Matching, 7 Blood Products		

Printed or personally saved electronic copies of this document are considered uncontrolled. Access the current version from the WNHS website.