TRANSFUSION MEDICINE PROTOCOLS

Prothrombinex™-VF

This document should be read in conjunction with the Disclaimer

DESCRIPTION	Prothrombinex™-VF (Factors II, IX & X)
SPECIFICATIONS	Coagulation Factors II (500 IU), IX (500 IU), X (500 IU), Antithrombin III (25 IU) and Heparin (200 IU). Prothrombinex® - VF Product Information
VIAL SIZE	500 IU
INDICATIONS	Treatment and perioperative prophylaxis of bleeding in acquired deficiency of prothrombin complex factors, such as deficiency caused by treatment with vitamin K antagonists, or in case of overdose of vitamin K antagonists, when rapid correction of the deficiency is required. Prevention and treatment of bleeding in patients with acquired or congenital factor deficiency e.g. reversal of warfarin therapy. Note: Prothrombinex™-VF should NOT be used for prophylaxis or treatment of haemorrhage in patients with Haemophilia B.
CONTRAINDICATIONS AND PRECAUTIONS	Hypersensitivity to the active substances or to any of the excipients including known allergy to heparin or history of heparin-induced thrombocytopenia (HIT). Prothrombinex™-VF is also contraindicated in patients who have evidence of active thrombosis or disseminated intravascular coagulation (DIC). Prothrombinex™-VF should not be used for prophylaxis or treatment of haemorrhage in patients with Haemophilia B.
CONSUMER INFORMATION	Prothrombinex™ - VF Consumer Medicine Information
CONSENT	Manufactured from pooled human plasma. Written consent to blood products required. Transfusion Medicine Protocol Blood Product Prescription, Informed Consent. And Refusal

DOSE	The full Prothrombinex™ - VF product information should be read prior to prescribing or administering Prothrombinex®- VF. Dosage and administration should be discussed with the Consultant Haematologist. Dosage varies from 20-30 IU/kg for minor haemorrhage up to 50 IU/kg for moderate to severe haemorrhage. Exact loading and maintenance doses and dosing intervals should be based on the patient's clinical condition, response to therapy and relevant laboratory tests.
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. • Prothrombinex®-VF is supplied as a freeze-dried powder with a 20mL ampoule of water for injection (WFI) and one Mix2Vial filter transfer set. • Before reconstitution allow the product to reach room temperature. • Follow the instructions on the box inside lid/ARCBS leaflet regarding the use of the Mix2Vial transfer system or click on the link How to use the 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. • Administered IV as a bolus, as a rate not exceeding 3 mL per minute. • Do not mix/piggy back this product with other medications or IV fluids/blood products.
OBSERVATIONS	• Bolus doses must be administered under constant visual observation. • Observe for signs of any adverse reaction and tissue infiltration. Undertake observations as for all blood products. Vital signs (temperature, pulse, respiration, blood pressure) must be recorded on the observation chart. • Monitor patient for at least 10 minutes post administration.

ADVERSE REACTIONS	Symptoms may include: fever, chills, dizziness, nausea or vomiting, itching, skin rash, tightness of the chest, wheezing or breathlessness. For more information refer to the Prothrombinex™ - VF product information Adverse reactions should be reported to the Clinical Haematologist and TMU. Refer to Transfusion Reaction and Adverse Event Management and Reporting, as a guide to further treatment and management of the patient.
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

- CSL Global Prothrombinex™-VF
- CSL Prothrombinex™ - VF product information
- Australian Red Cross Blood Service – 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
- National Safety and Quality Health Service Standards, October 2012. Standard 7: Blood and Blood Products
- Flippin' Blood BloodSafe SA / ARCBS Second Edition June 2012 http://resources.transfusion.com.au/cdm/ref/collection/p16691coll1/id/20

Related WNHS policies, procedures and guidelines

- Neonatology Clinical Care Guidelines
- Obstetrics and Gynaecology Clinical Guidelines
- Blood Product Prescription Consent and Refusal
- WNHS Pharmacy Medication Checking and Administration
- Major Haemorrhage and Urgent Transfusion Requests

File path:	WNHS.HAEM.ProthrombinexVF		
Keywords:	Blood Transfusion, Blood products, plasma derived blood products. Blood bank, transfusion medicine unit, blood bank scientist, major haemorrhage, coagulopathy, lyophilised high-purity human factor IX factor II, factor X, antithrombin Prothrombinex, , clotting factors, administration of prothrombinex, indications for prothrombinex, side effects of prothrombinex, contraindication to prothrombinex		
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 11 2016	Next review date:	01 12 2019
Endorsed by:	KEMH Hospital Transfusion Committee	Date:	01 12 2016
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.			