12.7 PROTHROMBINEX VF (FACTORs II IX AND X)

DESCRIPTION

Each pack contains one vial of lyophilised high-purity human factor IX (500 IU), factor II (500 IU), factor X (500 IU), antithrombin (25 IU) and heparin (200 IU), one ampoule of Water for Injection BP and a filter needle.

INDICATIONS

Prothrombinex is indicated only as directed by the Consultant Haematologist. For the prophylaxis and treatment of bleeding in patients with single or multiple congenital deficiencies of factor II or X and in patients with single or multiple acquired prothrombin complex factor deficiency requiring partial or complete reversal (e.g. Reversal of Warfarin anticoagulant therapy)

Note: Prothrombinex should NOT be used for prophylaxis or treatment of haemorrhage in patients with Haemophilia B.

CONTRAINDICATIONS

Prothrombinex should NOT be used in patients showing clinical or laboratory signs of thrombosis or DIC.

Prothrombinex should NOT be used for prophylaxis or treatment of haemorrhage in patients with Haemophilia B.

DOSE AND ADMINISTRATION

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

- Prothrombinex 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
- Dissolve the Prothrombinex by gentle swirling. Do not shake.
- A clear or slightly opalescent solution is obtained within 10 minutes. If clots or a gel form return the product to the Blood Bank.
- Infuse slowly intravenously approximately 3mL/minute.

For further product information see the CSL website Prothrombinex
REFERENCES

ARCBS Transfusion Medicine Manual is available at www.transfusion.com.au

ARCBS Immunoglobulin Information Factor Concentrates

CSL Product Information Prothrombinex