

**Doncaster and Bassetlaw Hospital NHS Foundation
Trust**

**Formulary Guidance for the Use of Human
Prothrombin Complex - Beriplex**

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Protocol for Use of Beriplex

Beriplex is the brand name for the human prothrombin complex used in this Trust. It contains the clotting factors II, VII, IX and X (the Vitamin K dependent clotting factors).

Beriplex is used for the emergency treatment of life-threatening haemorrhage. Please seek advice from the Consultant Haematologist on call if there is any doubt regarding its use

If Beriplex is to be administered for an indication other than major bleeding in patients taking oral anticoagulants, then the patient must be discussed with the Consultant Haematologist on call.

For patients on dabigatran, idarucizumab may be preferred over beriplex in patients admitted on dabigatran needing urgent reversal – seek Consultant Haematologist advice, if required.

Likewise, andexanet alfa may be preferred over beriplex in patients admitted on apixaban or rivaroxaban with life-threatening or uncontrolled bleeding – seek Consultant Haematologist advice, if required.

Indications for use

- **Life/limb-threatening haemorrhage**, e.g. intra-cranial or massive gastro-intestinal bleeds in a patient taking oral anticoagulants
- **Reversal of anticoagulation for emergency surgery (if the risks and benefits of using Beriplex are not clear, please discuss with Consultant Haematologist)**
- **Head injury patients on oral anticoagulants presenting with a strong suspicion of intracerebral bleed should have their anticoagulation reversed before the results of any investigations**

Cautions and warnings

Beriplex may induce a prothrombotic state in some patients. It should therefore be **used with caution** in patients with DIC, decompensated liver disease, CHD or MI, in post-operative patients and in neonates.

Viral safety

Beriplex (human prothrombin complex or prothrombin complex concentrate, PCC) is derived from pooled human plasma, as such there is a theoretical risk of transmission of virus or other infective pathogens.

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You must record the batch number of any Beriplex administered in the patients' notes and supply patient details to pharmacy when stock is taken or used. This is to facilitate patient tracing in the event of a recall

Contra-indication

Known Hypersensitivity to PCC.

Known history of Heparin Induced Thrombocytopenia

Monitoring

- **For patients given Beriplex on a vitamin K antagonist such as warfarin a repeat INR should be done 30 minutes after administration of beriplex. If the INR is still raised further doses of beriplex may be needed. This should be discussed with the consultant haematologist on call.**

Obtaining Beriplex

A supply of Beriplex is held at the following locations:

- 1. Doncaster Royal Infirmary Dispensary**
- 2. Bassetlaw Hospital Pharmacy**

It is held as stock on the following wards/departments

- 1. Accident and Emergency, Bassetlaw Hospital**
- 2. Accident and Emergency , DRI**
- 3. Main Theatres DRI**
- 4. Department of Critical Care, DRI**

and in the following Emergency Cupboards

- 1. Doncaster Royal Infirmary:** In the Emergency Drug Cupboard. This is located in the emergency cupboard in the pharmacy department (old waiting area). The key is held by DRI Switchboard.
- 2. Bassetlaw Hospital:** In the Emergency Drug Cupboard. This is located inside the first set of double doors leading in to the pharmacy department. A key is held by the nursing staff on ITU and on the ATC.

During Pharmacy opening hours contact the ward based Clinical Pharmacist who will arrange the supply.

Out of hours Beriplex may be obtained directly from the Emergency Drug Cupboard.

You must complete the Beriplex Emergency Store Supply Sheet (see Appendix 1) that identifies the patient you have taken the stock for. This is necessary to ensure stock is replaced and a register of patients is maintained.

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Replacing Beriplex as Ward Stock

For those areas that hold Beriplex as ward stock, the stock is held on the location 'Named Patient Supply'. This means that stock will not be topped up by the routine pharmacy stock system.

To replace stock you must complete the Beriplex Stock Re-Supply Sheet (see Appendix 2). Complete the sheet with the patients detail and quantities of Beriplex used. Any waste must also be recorded to ensure stock is accounted for and replaced.

Dose

(Note that the dose of Beriplex is expressed as the Factor IX concentration. Three vial sizes are available; when reconstituted they contain 1000 units in 40ml, 500 units in 20ml and 250 units in 10ml)

- For patients taking DOACs (e.g. apixaban, rivaroxaban, edoxaban, dabigatran), the dose should be 50 units/kg.
- For patients taking warfarin, the dose is **dependent on the INR** and on the **patient's weight**. The dose can be calculated from the table below.
n.b. Beriplex for this indication should be given in conjunction with vitamin k 5mg iv)

INR	2.0 - 3.9	25 units/kg (equivalent to 1ml/kg)
	4.0 - 6.0	35 units/kg (equivalent to 1.4ml/kg)
	> 6.0	50 units/kg (equivalent to 2ml/kg)

The maximum dose in either case is 5000 units.

Reconstitution

The pack of Beriplex contains the product, diluent and a transfer set (Mix2Vial package). The reconstituted solution should be used immediately.

Bring the solvent to room temperature.

Ensure that product and diluent vial flip caps are removed and the stoppers are treated with an aseptic solution and allowed to dry prior to opening the Mix2Vial package.

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 1	1. Open the Mix2Vial package by peeling away the lid.
 2	2. Place the diluent vial on an even, clean surface and hold the vial tight. Take the Mix2Vial together with the package and push the blue end straight down through the diluent stopper.
 3	3. Carefully remove the package from the Mix2Vial set. Make sure that you only pull up the package and not the Mix2Vial set.
 4	4. Place the product vial on an even and firm surface. Invert the diluent vial with the Mix2Vial set attached and push the transparent adapter straight down through the product vial stopper. The diluent will automatically flow into the product vial.
 5	5. With one hand hold the product-side of the Mix2Vial set, hold the diluent-side with the other hand and unscrew the set into two pieces. Discard the diluent vial with the blue part attached.
 6	6. Gently swirl the product vial until the substance is fully dissolved. Do not shake. Do not use the preparation if the solution doesn't dissolve completely or contains particles.
 7	7. Draw air into an empty, sterile syringe. While the product vial is upright, connect the syringe to the Mix2Vial's Luer Lock fitting. Inject air into the product vial.

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Withdrawal and application

	8. While keeping the syringe plunger pressed, invert the system upside down and draw the concentrate into the syringe by pulling the plunger back slowly.
	9. Now that the concentrate has been transferred into the syringe, firmly hold on to the barrel of the syringe (keeping the syringe plunger facing down) and disconnect the Mix2Vial set from the syringe. 10 Label each syringe prepared in accordance with the Intravenous Medicines Policy (see PAT/MM5 section 6.5).

Administration

Because of the risk of viral transmission **you must record the batch number of any Beriplex administered** in the patients notes

Beriplex is administered by slow IV injection at a maximum rate of 200 units/minute.

No blood should be allowed to flow into the syringe of Beriplex during administration. This is due to the risk of clots forming in the syringe.

If allergic or anaphylactic type reactions occur, the administration of Beriplex should be stopped immediately.

Beriplex **must not** be mixed with any other medicinal or blood product and must be given via a separate IV line or cannula that has been flushed with water for injections before use.

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Appendix 1 - Record of Beriplex Injection taken from the Emergency Store

Supplies of Beriplex need to be allocated to specific patients. Please record the patient details for the Beriplex taken below:

Date _____

Ward / Department _____

Patient Name _____

Hospital Number (if known) _____

Details of Beriplex Taken

Ward Use			Pharmacy use	
Strength	Batch Number	Quantity Taken	Disp	Checked

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Appendix 2 - Re-Supply of Beriplex Injection as Ward Stock

Beriplex injection is listed on your stock list but will not be topped up. Supplies need to be allocated to specific patients.

To replenish supplies please forward this list of patients to the Pharmacy

Ward / Department _____

Date Administered	Patient Details

Details of Beriplex Administered

Ward Use			Pharmacy use	
Strength	Batch Number	Quantity Given	Disp	Checked

Details of Wasted

Ward Use		Pharmacy use	
Strength	Quantity wasted	Disp	Checked