Doncaster and Bassetlaw Hospital NHS Foundation Trust

Formulary Guidance for the Use of Human Prothrombin Complex - Beriplex

Reviewed by:

Roger Hancocks
Deputy Director of Pharmacy and Medicine Management

Dr Stuti Kaul
Consultant Haematologist

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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 in patients taking oral anticoagulants.

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 on a vitamin K antagonist, then the patient must be discussed with the Consultant Haematologist on call.

Indications for use

- Life-threatening haemorrhage, e.g. intra-cranial or massive gastrointestinal bleeds in a patient taking oral anticoagulants
- Reversal of anticoagulation for emergency surgery (Discuss with 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) is derived from pooled human plasma, as such there is a theoretical risk of transmission of virus or other infective pathogens.

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
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

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 the nursing staff on AMU.
2. Bassetlaw Hospital: In the Emergency Drug Cupboard. This is located inside the first set of double doors leading into 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.

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 NOACs (e.g. apixaban, rivaroxaban, 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.

<table>
<thead>
<tr>
<th>INR</th>
<th>Dose (units/kg)</th>
<th>Volume (ml/kg)</th>
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<tbody>
<tr>
<td>2.0 - 3.9</td>
<td>25</td>
<td>(equivalent to 1 ml/kg)</td>
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<tr>
<td>4.0 - 6.0</td>
<td>35</td>
<td>(equivalent to 1.4 ml/kg)</td>
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<tr>
<td>&gt; 6.0</td>
<td>50</td>
<td>(equivalent to 2 ml/kg)</td>
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The maximum dose in either case is 5000 units.

Reconstitution

The pack of Beriplex contains the product, diluent and a transfer set (Mix2 vial 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.

1. Open the Mix2Vial package by peeling away the lid.
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. Carefully remove the package from the Mix2Vial set. Make sure that you only pull up the package and not the Mix2Vial set.
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. 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. 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. 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.

**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.

Vitamin K 5mg by slow IV injection should be given at the same time as the Beriplex. This is because the effect of Beriplex on the INR is short-lasting and a rise in INR may be seen later as the effect wears off.
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

<table>
<thead>
<tr>
<th>Ward Use</th>
<th>Pharmacy use</th>
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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 __________________________________________

<table>
<thead>
<tr>
<th>Date Administered</th>
<th>Patient Details</th>
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Details of Beriplex Administered

<table>
<thead>
<tr>
<th>Ward Use</th>
<th>Pharmacy use</th>
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<tr>
<td>Strength</td>
<td>Batch Number</td>
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Details of Wasted

<table>
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<tr>
<th>Ward Use</th>
<th>Pharmacy use</th>
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<tbody>
<tr>
<td>Strength</td>
<td>Quantity wasted</td>
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Pharmacy use: After the supply is complete file this sheet in the Beriplex Register