Document Control

Title

Octaplex® Infusion for the Rapid Reversal of Oral Anticoagulation in the presence of life-, limb- or sight- threatening haemorrhage Standard Operating Procedure

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1.1	Sep 2010	Revision	Minor amendments by Corporate Affairs to document control report, filename and header and footer.
1.2	July 2011	Revision	Amendment to scope and identification to syringe pump agreed at Hospital Transfusion Team meeting 19th July 2011.
1.3	Jan 2014	Revision	Reviewed by HTT 21st Jan 2014. Update to section 5 re syringe pump. 6.2 to include Mix2Vial transfer set. 6.3 to include pressure setting for syringe pump.
1.4	Feb 2017	Revision	Updated to new Trust Template. References updated. Approved at HTT 23.02.17.
1.5	May 2019	Revision	Octaplex available on 1000unit or 500unit vial 6.3 Faster rate of infusion if clinical urgency demands 6.3 Recheck INR 15 minutes after infusion completed
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<tr><td>Consulted with the following stakeholders: (list all)
Hospital Transfusion Team
Hospital Transfusion Committee
Consultant Haematologists
Lead Clinicians
Senior Nurses</td><td>Contact responsible for implementation and monitoring compliance:
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1. Background

Octaplex® is a Prothrombin Complex Concentrate (PCC) used for the rapid reversal of oral anticoagulation in the presence of life-, limb- or sight-threatening haemorrhage with INR greater than 2.0. This document sets out Northern Devon Healthcare NHS Trust's (NDHT) procedure for the preparation and administration of Octaplex®. Staff are also asked to refer to the NDHT's Guidelines for the use of Octaplex®, NDHT Policy and SOPs for the prescribing, preparing and administering of injectable medicines.

Octaplex® is issued from the Transfusion Laboratory following authorisation from a Consultant who is familiar with the indications and contra-indications for its use.

Octaplex is supplied as a powder containing either 1000units or 500units per vial. A 40ml solvent for solution is provided with the 1000units vial and 20ml solvent for solution (water for injection) is provided with 500units vials.

2. Purpose

2.1. The Standard Operating Procedure (SOP) has been written to:

- Identify the procedure for the preparation and administration of Octaplex®.
- Reduce the risks associated with the provision of Octaplex® by identifying safe systems of work.

3. Scope

This Standard Operating Procedure (SOP) relates to the following staff groups who may be involved in the preparation and administration of Octaplex®:

- Registered nurses
- Operating Department Practitioners
- Medical staff

4. Location

This Standard Operating Procedure on the preparation and administration of Octaplex® can be implemented in all clinical areas where competent staff are available to undertake this role.

Staff undertaking this procedure must be able to demonstrate continued competence as per the organisations policy on assessing and maintaining competence.

5. Equipment

- Each Package of 500 units Octaplex® containing:
    - Powder in a vial with a rubber stopper and a flip off cap (1000units or 500units)
    - Diluent in a vial with a rubber stopper and a flip off cap (40mls or 20mls water for injection)
    - 1 Mix2Vial™ transfer set
- Non-sterile gloves
- 2% chlorhexidine gluconate in 70% alcohol wipes
- 50ml Luer-Lock syringe
- Medication label for syringe
- Blind hub (bung)
- IV extension set
- 0.9% sodium chloride flush
- Syringe pump (B/Braun Perfusor®)
- Sharps container

In addition, the patient will require a separate intravenous (IV) access for the Octaplex® infusion.

6. Procedure

6.1. Procedure for preparing the Octaplex® infusion

- Check prescription details carefully and confirm that they relate to the patient to be treated.
- Explain and discuss the procedure with the patient and gain consent.

- Ensure that the area in which the medicine is to be prepared is as clean, uncluttered and free from interruption and distraction as possible.

- Assemble all materials and equipment as listed in section 5.

- Check the following:

  o expiry dates

  o damage to containers, vials or packaging

  o that medicines were stored as recommended

- Check that:
  o the formulation, dose, diluent, infusion fluid and rate of administration correspond to the prescription and product information

  o the patient has no known allergy to the medicine

  o you understand the method of preparation.

- Prepare the medication label for the syringe.

6.2. Procedure for reconstituting Octaplex®

- Cleanse hands according to Trust policy.

- Warm the diluent (Water for Injection) and the powder in the closed vials up to room temperature as these are stored under controlled conditions in the Transfusion Laboratory.

- Use an aseptic non-touch technique, i.e. avoid touching areas where bacterial contamination may be introduced, e.g. syringe-tips, needles, vial tops.

- Remove the tamper-evident seals from the powder vial and the water vial and clean the rubber stoppers with 2% chlorhexidine gluconate in 70% alcohol and allow to dry.

- Place the water vial on an even surface.

- Remove the top of the Mix2Vial™ package. Do not remove the device from the package.

- Seat the blue end of the device on the water vial, using the blister pack as a holder. Push down until the spike penetrates the stopper and the device snaps in place.

- Remove the plastic package and discard. Take care not to touch the exposed end of the device.

- Turn the water vial upside down and insert the clear end into the powdered Octaplex® vial, pushing down until the spike penetrates the stopper and the device snaps in place.

- The water will automatically flow into the Octaplex® vial. Gently swirl the vial to make sure the Octaplex® is thoroughly mixed.

- Remove the water vial by turning it anti-clockwise. Attach a sterile, 50mL Luer-Lock syringe to the Octaplex® vial.

- Turn the Octaplex® vial upside down and withdraw the solution into the syringe. Remove the syringe by turning the barrel counter clockwise.

- Octaplex® dissolves quickly at room temperature to a colourless to slightly blue solution. If the powder fails to dissolve completely or an aggregate is formed, do not use the preparation.

- Attach a sterile IV extension administration set to the syringe and prime the line.

- Check the syringe for cracks or leaks and label with the following details:

  o name of the medicine
  o dose of medicine
  o route of administration
  o diluent and final volume
  o patient's name
  o date and time of preparation
  o name/initials of healthcare practitioner who prepared the infusion

6.3. Procedure for administering Octaplex®

- Ensure you are competent to use the selected syringe pump.

- Load the syringe securely in the syringe pump.

- Set the rate according to the prescription.

Octaplex® is administered at an initial rate of 1ml/minute (60mls/hr). This can be increased to 3mls/minute (180mls/hr) as tolerated and as recommended by the manufacturer. A faster rate of administration may be considered if clinical urgency demands.

For rapid infusions, it may be necessary to gradually increase the pressure setting of the syringe driver to the maximum setting of 9 (900mmHg). Be aware this will prolong the alarm reaction time.

- Check the patient's identity against the prescription, transfusion form and identity band, confirming details with the patient as appropriate.
- Use aseptic non-touch technique at all times.
- Clean the IV closed system with 2% chlorhexidine gluconate in 70% alcohol and allow to dry.
- Flush the vascular access device with 0.9% sodium chloride.
- Attach and secure the Octaplex® infusion, without delay, to the vascular access device.
- Sign and record the start time and batch numbers on the prescription chart and transfusion paperwork.
- Ensure the nurse call bell is within reach and ask the patient to report promptly any adverse effect.
- Monitor the patient, Early warning Score, IV access and rate of delivery throughout the infusion.
- If symptoms suggest allergic-anaphylactic reactions or thrombo-embolic events, the infusion must be discontinued immediately and appropriate treatment initiated.
- To comply with traceability requirements ensure correctly completed paperwork is returned to the Transfusion Laboratory.
- The patient's INR level should be repeated 15 minutes after completing the infusion to check the response.

7. References

- Octapharma (2016) Octaplex® Product Characteristics

8. Associated Documentation

8.1. Northern Devon Healthcare NHS Trust Policies for :

- Guidelines for the Use of Prothrombin Complex Concentrate (PCC) (Octaplex)
- NDHT Blood Transfusion Policy
- NDHT Injectable Medicines Policy
- NDHT Medicines Policy