



Pre-Hospital Care Standard Operating Procedure
Use of Human Prothrombin Complex (Octaplex®)

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APPROVAL/ ADOPTED:		
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Aims:

1. Describe the rationale for the pre-hospital administration of Octaplex.
2. Describe the steps to be followed in order to correctly administer Octaplex.
3. Illustrate the correct dosing regime for Octaplex to be administered by LAA crews.
4. Describe the administrative processes associated with the pre-hospital use of Octaplex.

Background:

Warfarin is an oral medication that inhibits Vitamin K participation in the synthesis of clotting factors. There are a number of reasons that a patient may be taking Warfarin, including recurrent deep vein thrombosis or pulmonary embolism, the presence of mechanical heart valves or chronic atrial fibrillation. The Vitamin K-dependent clotting factors are Factors II, VII, IX and X. Once synthesised, these clotting factors are present in blood, ready to be used in the clotting cascade for up to 72 hours. Warfarin inhibits the production of these factors. Octaplex is a human prothrombin complex derived from human donor plasma and contains all of the Vitamin K-dependent clotting factors. Octaplex is licensed for the emergency reversal of warfarin.

Warfarinised patients who sustain a head injury or suffer a spontaneous intra-cerebral bleed are at increased risk of developing surgically significant intracranial haematoma. This group of patients may deteriorate more rapidly than those patients with normal clotting. Emergency reversal of Warfarin can prevent or slow the expansion of intracranial haematoma and may reduce the risk of catastrophic clinical deterioration occurring prior to definitive neurosurgical care. Prothrombin complex concentrates rapidly correct coagulopathy in patients who are taking Warfarin and should be given to selected patients at the earliest opportunity.

Pre-hospital physicians have the opportunity to deliver this intervention at a much earlier stage than is currently achievable even with a pre-alert to the hospital. Early reversal not only potentially limits the expansion of the haematoma but may also reduce the time to neurosurgical intervention.

Equipment:

London's Air Ambulance medical teams carry Octaplex in the aircraft and on all rapid response vehicles. This drug is stored in a red insulated bag.

Octaplex insulated bag contains:

- 6 boxes of Octaplex (3000iu total)
- CoaguChek XS plus device (fully charged unit)
- Testing strips and lancets
- Aide-memoire for reconstitution
- 3 x green patient wristbands and security devices
- 3 x Octaplex stickers

Octaplex can be replaced from the supply in the fridge or be obtained from pharmacy.

Policy:

Indications for use

- Confirmed or strongly suspected to be taking Warfarin
AND
- Clinical suspicion of intracranial haemorrhage
AND
- INR confirmed to be greater than 2 on near-patient testing

Patients with an INR of less than 2, but who otherwise meet the criteria for administration should also be discussed with the duty consultant in pre-hospital care.

Warfarinised patients with multiple injuries and suspected bleeding

Octaplex should not usually be given to Code Red patients.

Patients who are taking Warfarin and who are thought to be bleeding from injuries other than intracranial haemorrhage (and in particular, patients for whom a Code Red has been declared) may benefit from reversal of anticoagulation. These cases must be discussed with the duty consultant in pre-hospital care. Reversal of anticoagulation in these patients will typically occur in hospital, with blood products, as part of a massive transfusion protocol.

If you have any queries as to whether it is appropriate to administer Octaplex – you must call the duty consultant in pre-hospital care.

Administration of Octaplex

Dose and reconstitution

The dose is based on the patient's weight and the measured INR. Octaplex is given immediately after reconstitution as a slow intravenous bolus over 15-30 minutes. The maximum dose is 120mls of reconstituted solution (6 vials). The dose in **mls of reconstituted** solution is given in the table below.

Octaplex dosing chart			
Weight / INR	2 – 2.5	2.6 – 3.5	>3.5
40kg	40mls	60mls	80mls
45kg	40mls	60mls	100mls
50kg	60mls	80mls	100mls
55kg	60mls	80mls	120mls
60kg	60mls	100mls	120mls
65kg	60mls	100mls	120mls
70kg	80mls	100mls	120mls
75kg	80mls	120mls	120mls
80kg	80mls	120mls	120mls
85kg	80mls	120mls	120mls
90kg	100mls	120mls	120mls
95kg	100mls	120mls	120mls
100kg	100mls	120mls	120mls

The packaging contains a double-ended needle. Both the powder vial and the water vial have a rubber stopper. Perforate the water vial first with one end of the double-ended needle, and then perforate the powder vial with the other end. A vacuum draws in the water. Once all the water is drawn in, remove the needle and empty water vial and slowly rotate the powder vial until the powder is completely dissolved. Do not shake. Use the filter needle to perforate the powder vial and attach a 20ml syringe to draw up the contents of the vial.

In order to avoid extended scene times, Octaplex will usually be reconstituted and administered en route to hospital, unless there are additional personnel on scene who have been trained to fulfil this role.

Documentation and traceability

- The Octaplex administration sticker must be completed and attached to the reverse side of the HEMS mission sheet. The batch no must be recorded on the sticker.
- A green "Octaplex" wrist band must be attached to the patient.
- Hand over must explicitly state that Octaplex has been administered.
- A photocopy of both sides of the run sheet (including the sticker) must be handed to the Team Leader / scribe to form part of the in-patient record.
- When completing the HEMS database – ensure that Octaplex is selected on the drop down interventions menu.
- For every patient who receives Octaplex, the spreadsheet on the Q drive must be completed. This acts as a traceability record for blood product administration and a trigger for re-stocking from pharmacy.
- The HEMS registrar responsible for pharmacy liaison will e-mail the updated spreadsheet to pharmacy on a monthly basis.

References

Prothrombin complex concentrates: an update. Franchini M, Lippi G. Blood Transfus 2010;8:149-54
Emergency reversal of anticoagulation with a three-factor prothrombin complex concentrate in patients with intracranial haemorrhage. Imberti et al. Blood Transfusion 2011;9:148-55

Algorithm for pre-hospital Octaplex administration

