

PCC OCTAPLEX

To be read in conjunction with Warfarin Reversal Management

Ref No. 2506

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Flow Chart For Emergency Departments

Indications for use of PCC Octaplex in the Emergency Department:

PCC Octaplex is only indicated in the reversal of warfarin.

Reversal of Warfarin in:

- Patients with intracranial or rapid onset neurological signs, intra-ocular (not conjunctival), compartment syndrome, pericardial bleeds or those with active bleeding and shock in need of urgent clinical assessment.
- Significant bleeding without haemodynamic compromise
- Clinically essential immediate operation

Contraindications:

Absolute

- Known hypersensitivity to the active substance or any of the excipients

Relative (to be made on a case by case basis)

- Patients at risk of thromboembolic phenomena
- Patient with Disseminated Intravascular Coagulation (DIC).

Product Information

- Octaplex is a pooled plasma coagulation factor concentrate. Each vial contains coagulation factors II (220 – 760IU), VII (180 – 480IU), IX (500IU) and X (360 – 600IU). It also contains protein C, protein S, albumin, heparin and sodium citrate.
- 25 i.u/ml in 20 ml bottles (500 i.u. bottles)
- Octaplex is licensed for use for the treatment of bleeding and peri-operative prophylaxis of bleeding in patients receiving Warfarin. It is also licensed for treatment of bleeding and peri-

- operative prophylaxis in congenital deficiency of any of the vitamin K dependent coagulation factors (FII, FVII, FIX & FX) when purified specific coagulation products are not available.
- PCC Octaplex provides a more rapid and effective reversal of Warfarin at a lower volume than human plasma.
 - Side effects relating to the administration of PCC Octaplex should be carefully outlined to the patient prior to administration – potential adverse effects of PCC Octaplex are as follows:
 - Hypersensitivity or allergic reactions.
 - Development of antibodies to one or more of the prothrombin complex constituents.
 - Risk of thrombosis.
 - Rare cases of development of heparin-associated fall in platelet count.

Process of ordering PCC Octaplex

- Discuss the case with the on-call haematology consultant
- Order PCC Octaplex on “Review” via the “Test Order” section
- Dose is dependent on the patient weight and the INR
- The dose to be given will be determined by the on-call haematologist
- If INR is unknown and the clinical circumstances require immediate reversal of warfarin then use 2ml/kg
- Maximum dose is 120 ml/3,000 units

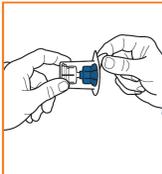
Prescription

- Vitamin K MUST be prescribed and given prior to PCC Octaplex
- PCC Octaplex must be prescribed on the in-patient drug chart on the blood product prescription chart and attached to the in-patient drug chart
- Each bottle must be prescribed independently
- The product is reconstituted from a dried powder using the supplied diluent, using an aseptic technique. It should then be administered as an IV infusion initially at 1ml per minute increasing to 3ml per minute in the absence of any allergic or anaphylactic reactions.
- Each bottle comes with a detachable sticker. This sticker must be stuck on patients notes, as you would do for a blood transfusion.

Monitoring of INR

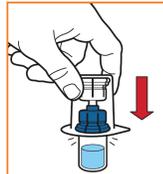
- Once PCC Octaplex has been given, wait 20 minutes and perform another clotting screen and assess the degree of correction of INR.
- Seek further advice if no improvement takes place.
- The degree of reversal must be decided on an individual basis. All patients with bleeding should be evaluated to identify if there is a local anatomical reason for bleeding.

Follow the hospital's aseptic procedures at all times. Working on a clean flat surface, remove the vials from the outer packaging and remove the flip top lids. Disinfect the vial injection sites with an alcohol swab.



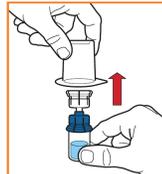
Step 1

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



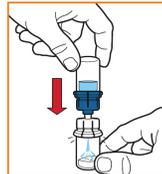
Step 2

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.



Step 3

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



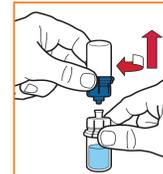
Step 4

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.



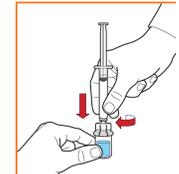
Step 5

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



Step 6

Remove the water vial by turning it anti-clockwise. Attach a syringe to the octaplex® vial.



Step 7

Turn the octaplex® vial upside down and withdraw the solution into the syringe. Remove the syringe by turning the barrel counter clockwise. octaplex® is now ready for administration.

Further product information can be found on the reverse of the reconstitution guide pictured above and also the information leaflet provided in the product box.