Octaplex

TRANSFUSION MEDICINE SERVICES

OTHER NAMES	CLASSIFICATION	ALERTS
Prothrombin Complex Concentrate PCC	Coagulation Factor Product Coagulation factors: II, VII, IX, and X and Proteins C & S	Contains human plamsa

PREPARATION and ADMINISTRATION

Reconstitution

Diluent: setrile water for injection in 20 mL or 40 mL volumes

See page 4 for reconstitution steps or video link at https://vimeo.com/769078376

After reconstitution, inspect visually for particulate matter and discoloration prior to administration.

Attach a plastic sterile disposable syringe to the transparent part of Mix2Vial™. Invert the system and draw the reconstituted product into the syringe.

Once the solution has been transferred into the syringe, firmly hold the barrel of the syringe (keeping it facing down) and detach the Mix2Vial™ from the syringe.

The solution may be administered IV Direct (Professionals performing these restricted activities must have received authorization from their regulatory College and have the knowledge and skill to perform the skill competently),

Otherwise administer with a syringe pump or inject solution into an empty 50 mL IV bag and infuse via volume pump.

IV Direct	Intermittent Infusion	Continuous Infusion
As per employment authorization and skillset Administer dose as reconstituted solution at an initial rate of 1 ml per minute, followed by 2-3 ml per minute, if patient is tolerating well.	**IV Bag (large volume pump)**	**IV Bag (large volume pump)**
	Administer dose as reconstituted solution at an initial rate of 1 ml per minute (60ml/h), followed by 2-3 ml per minute (120-180 mL/h), if patient is tolerating well.	Not applicable
	Syringe (syringe pump)	**Syringe (syringe pump)**
	Administer dose as reconstituted solution at an initial rate of 1 ml per minute (60ml/h), followed by 2-3 ml per minute (120-180 mL/h), if patient is tolerating well.	Not applicable

Note: The patient's pulse rate should be measured before and during the injection. If a marked increase in the pulse rate occurs, the injection speed must be reduced or the administration must be interrupted.

Requirements and Monitoring

Because of the risk of thromboembolic complications, **close monitoring should be exercised when administering to patients with a history of coronary heart disease, myocardial infarction, to patients with liver disease, to peri- or postoperative patients, or to patients at risk of thromboembolic events or disseminated intravascular coagulation.**

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Baseline vitals within 60 min before starting infusion. Reassess 15 min after starting infusion under direct observation. If transfusion is less than one hour, check vital signs: before initiation, 15 minutes after initiation, and immediately following the transfusion. Inpatients should be observed for the presence of thrombosis for 24 hours post infusion and upon discharge. **Document all vitals taken**.

Blood pressure via cuff or arterial line
Temperature
Heart Rate
Respirations
Lung sounds in non-verbal, non-oriented or pediatric patients and patients with CHF or pulmonary dysfunction

Keep unopened back up bag of NS and standard IV tubing nearby for prompt response if an adverse event (AE) occurs.

INDICATIONS

Treatment of bleeding and perioperative prophylaxis of bleeding in acquired deficiency of the prothrombin complex coagulation factors, such as deficiency caused by treatment with vitamin K antagonists, or in case of overdose of vitamin K antagonists, when rapid correction of the deficiency is required

ADVERSE EFFECTS

Adverse reactions may include: Allergic-type hypersensitivity reactions including anaphylaxis have been reported and have manifested as pruritus, rash, urticaria, local site reactions, hives, facial swelling, dizziness, hypotension, nausea, chest discomfort, cough, dyspnea, wheezing, flushing, discomfort (generalized) and fatigue.

If an AE is suspected: stop the transfusion, disconnect and cap the blood tubing, intiate the backup line of NS and consult the authorized perscriber (AP) for medical management. Notify the TM lab of a suspected reaction.

- Review the product lot number, TM tag and patient ID to rule out a verification (clerical) error and that the expiry date and time has not passed.
- Resume transfusion cautiously as directed by AP. Directly observe patient x5min then closely observe x10min.
- Ensure TM tag, along with a copy of the documented clinical data and interventions are sent to TM lab once transfusion is discontinued or completed.
- If the transfusion must be discontinued and a transfusion reaction workup is ordered, send the additional following items to TM lab:
  i. Blood work (1 Red top and 1 EDTA (Pink or Lavender top))
     * possible exception for pediatric patient: lab testing to be performed at discretion of Hematopathologist
  ii. Product and administration set (ensure set is safely capped)

Note: AP may also require additional testing such as: blood cultures, chest x-ray, EKG, or urine specimen

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DOSAGE

	INR 1.7- 5.0	INR greater than or equal to 5.1 OR major bleeding with an unknown INR OR intracranial hemorrhage
Dose of PCC	40 mL	80 mL

- If the INR is greater than 1.7 after initial or subsequent doses and the patient continues to bleed, an additional dose of 20 mL of PCC may be given.
- A higher or second dose may be needed in extremes of INR or weight.

The maximum dose of Octaplex® is 120 ml.

COMPATIBILITY, STABILITY

- Compatible with NS or dextrose 5% in water (D5W)
- Incompatible with all other IV formulations
- Single use vials. Do not use past expire date
- Do not dilute in any IV solutions
- Protect vials from light
- Do not store unused vials in refrigerator. Adminster at room temperature

DOSAGE FORMS

- Supplied by Transfusion Medicine

MISCELLANEOUS

- Ensure patient is properly hydrated before starting infusion to limit adverse events.

LIBRARIES

- Searchable Drug Library Document

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RECONSTITUTION

See below for instructions for reconstitution:

1. If the octaplex® powder and water for injection (WFI) are not already at room temperature, warm up the closed vials to room temperature (maximum 37°C). This temperature should be maintained during reconstitution. If a water bath is used to warm the WFI, care should be taken to ensure the water does not come into contact with the rubber stopper or closure system of the vials.

Fig. 1

2. Remove the flip caps from the octaplex® vial and the WFI vial and clean the rubber stoppers with an alcohol swab.

Fig. 2

3. Peel away the lid of the outer package of the Mix2Vial™ transfer set. Place the WFI vial on an even surface and hold the vial firmly. Push the blue plastic cannula of the Mix2Vial™ firmly through the rubber stopper of the WFI vial in one swift motion (Fig. 1). While holding onto the WFI vial, carefully remove the outer package from the Mix2Vial™, being careful to leave the Mix2Vial™ attached firmly to the WFI vial (Fig. 2).

4. With the octaplex® vial held firmly on an even surface, quickly invert the WFI vial (with the Mix2Vial™ attached), push the transparent plastic cannula end of the Mix2Vial™ firmly through the stopper of the octaplex® vial and hold the downward pressure (Fig. 3). The WFI will be drawn into the octaplex® vial by vacuum.

Fig. 3

Fig. 4

5. With both vials still attached, slowly rotate the octaplex® vial to ensure the product is fully dissolved to a clear or slightly opalescent solution. Once the contents of the octaplex® vial are dissolved, firmly hold both the transparent and blue parts of the Mix2Vial™. Unscrew the Mix2Vial™ into two separate pieces with the vials still attached (Fig. 4) and discard the empty WFI vial and the blue part of the Mix2Vial™.

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REFERENCES

- CL-BP-030, IWK-625 Blood Component and Blood Product Administration – Policy and Procedure
- Octaplex product monograph. Found at https://www.octapharma.ca/en/therapies/product-overview