Beriplex

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 plasma

PREPARATION and ADMINISTRATION

Reconstitution

Diluent: setrile water for injection in 20 mL (500 unit) and 40 mL (1000 unit) volumes

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

Prior to administration, inspect visually for particulate matter and discoloration.

Reconstituted 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 (less than 60 mL) or inject solution into an empty 50-200 mL IV bag and infuse via volume pump.

IV Direct	Intermittent Infusion	Continuous Infusion
As per employment authorization and skillset Administer IV Direct at 2-3 mL/min, increasing to **8 ml per minute (max)**, as tolerated.	**IV Bag (large volume pump)**	**IV Bag (large volume pump)**
	Administer intravenously by a separate infusion line at 2-3 mL/min (120-180 mL/h), increasing to **8 mL/min (480 mL/h maximum**, as tolerated.	Not applicable
	Syringe (syringe pump)	**Syringe (syringe pump)**
	Administer intravenously by a separate infusion line at 2-3 mL/min (120-180 mL/h), increasing to **8 mL/min (480 mL/h) maximum**, as tolerated.	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

Beriplex® P/N (Human prothrombin complex) is indicated in adults (≥ 18 years of age) for the 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

Bleeding and perioperative prophylaxis of bleedings during vitamin K antagonist treatment.

The dose will depend on the International Normalised Ratio (INR) before treatment and the targeted INR. The pre-treatment INR should be measured as close as possible to the time of dosing in order to calculate the appropriate dose of Beriplex. In the following table, approximate doses (mL/kg body weight [b.w.] of the reconstituted product and IU of Factor IX/kg b.w.) required for normalisation of INR (e.g. ≤ 1.3) at different initial INR levels are given.

Pre-treatment INR*	2.0 – 3.9	4.0 – 6.0	> 6.0
Approximate dose mL/kg b.w. †	1	1.4	2
Approximate dose IU (Factor IX)/kg b.w.	25	35	50

* INR = [prothrombin time of patient's sample / prothrombin time of control plasma]ISI. The results are used to calculate the relative sensitivity of the sample compared with the WHO standard International Sensitivity Index (ISI).

† Dose based on actual potency stated on the vial, which vary from 20-31 Factor IX IU/mL after reconstitution.

Dose is based on body weight up to but not exceeding 100 kg. For patients weighing more than 100 kg the maximum single dose (IU of Factor IX) should therefore not exceed 2500 IU for an INR of 2.0 – 3.9, 3500 IU for an INR of 4.0 – 6.0 and 5000 IU for an INR of > 6.0.

The maximum dose of Beriplex® P/N is 200 mL.

Administration of Vitamin K 10mg IV over 30 minutes is recommended with the initial dose.
Oral, subcutaneous and intramuscular routes are not recommended.

The INR should be checked at 10-15 minutes after the completion of the infusion

COMPATIBILITY, STABILITY

- Compatible with NS
- 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

Bring the Product and the solvent (diluent) to room temperature. Ensure that the product and solvent vial flip caps are removed and that the stoppers are treated with an antiseptic solution and allowed to dry prior to opening the Mix2Vial® package.

1. Open the Mix2Vial® package by peeling off the lid. Do **not** remove the Mix2Vial® from the blister package!

2. Place the solvent vial on an even, clean surface and hold the vial tight. Take the Mix2Vial® together with the blister package and push the spike of the **blue** adapter end **straight down** through the solvent vial stopper.

3. Carefully remove the blister package from the Mix2Vial® set by holding at the rim, and pulling **vertically** upwards. Make sure that you only pull away the blister package and not the Mix2Vial® set.

4. Place the **product vial** on an even and firm surface. Invert the solvent vial with the Mix2Vial® set attached and push the spike of the **transparent** adapter end **straight down** through the product vial stopper. The solvent will automatically flow into the product vial.

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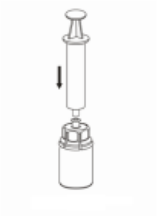
5. With one hand grasp the product-side of the Mix2Vial® set, and with the other hand grasp the solvent-side and unscrew counterclockwise the set carefully into two pieces. Discard the solvent vial with the blue Mix2Vial® adapter attached.

6. Gently swirl the product vial with the transparent adapter attached until the substance is fully dissolved. Do not shake.

7. Draw air into an empty, sterile syringe. While the product vial is upright, connect the syringe to the Mix2Vial®'s Luer Lock fitting by screwing clockwise. Inject air into the product vial.



Withdrawal and application:

8. While keeping the syringe plunger pressed, turn the system upside down and draw the solution into the syringe by pulling the plunger back slowly.

9. Now that the solution has been transferred into the syringe, firmly hold on to the barrel of the syringe (keeping the syringe plunger facing down) and disconnect the transparent Mix2Vial® adapter from the syringe by unscrewing counterclockwise.

REFERENCES

- CL-BP-030, IWK-625 Blood Component and Blood Product Administration - Policy and Procedure
- Beriplex product monograph. Found at https://www.cslbehring.ca/products/product-list