Benefix

TRANSFUSION MEDICINE SERVICES

CLASSIFICATION	ALERTS
Recombinant Coagulation Factor IX Product. Standard Half-life	None

PREPARATION and ADMINISTRATION

Benefix is a recombinant Factor VIII product that does not contain plasma therefore blood consent is not required.

Reconstitution

Diluent: 0.234% sodium chloride diluent for injection

See pages 2-4 for reconstitution steps -administer within 3 hours of reconstitution

After reconstitution, inspect visually for particulate matter prior to administration

IV Direct	Intermittent Infusion	Continuous Infusion
IV Direct is the recommended route of administration. Professionals performing these restricted activities must have received authorization from their regulatory College and have the knowledge and skill to perform the skill competently Administer dose over several minutes as tolerated by patient's comfort level. If no indwelling IV, use the butterfly and supplies provided in the box.	**IV Bag (large volume pump)** Not Recommended **Syringe (syringe pump)** Not Recommended	**IV Bag (large volume pump)** Not applicable **Syringe (syringe pump)** Not applicable

Requirements and Monitoring

Baseline vitals before starting infusion. Reassess 15 min after infusion.

Patients who have had several doses without incident do not require vitals unless clinical context warrants them.

Blood pressure via cuff or arterial line
Temperature
Heart Rate
Respirations

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

INDICATIONS

Indicated for adult for adults and children with hemophilia B for:

- Routine prophylaxis in patients with hemophilia B (Congenital factor IX deficiency)
- The control and prevention of bleeding episodes and, perioperative management

ADVERSE EFFECTS

The following reactions may be observed after administration: headache, fever, chills, flushing, nausea, vomiting, lethargy, or manifestations of allergic reactions.

If an AE is suspected: stop the infusion, and consult the authorized prescriber (AP) for medical management. Notify the TM lab of a suspected reaction.

CLASSIFICATION	ALERTS
Recombinant Coagulation Factor IX Product. Standard Half-life	None

- 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 infusion 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 infusion is discontinued or completed.

DOSAGE

Consult the Bleeding Disorders Clinic or the Hematologist on call for appropriate dosing prior to initial dose:

Ask patient if they have a Factor First card supplying the recommended treatment and dosage

(Adult) Hereditary Bleeding Disorder Clinic 902-473-5612. After hours call 902-473-2220.
(Pediatric) IWK Bleeding Disorder Clinic 902-470-8752. After hours call 1-888-470-8888.

For patient specific dosing at the IWK please see Complex Care Management Plan in the "Alerts" section under "Scanned Permanent Health Records" in the IWK MEDITECH MAGIC system.

COMPATIBILITY, STABILITY

- Compatible with NS
- Single use vials. Do not use past expiry date
- Do not dilute in any IV solutions
- Prior to reconstitution, vials should be stored in their supplied box to protect from light
- Do not store unused vials in refrigerator. Administer at room temperature

DOSAGE FORMS

- Supplied by Transfusion Medicine (Blood Bank)

MISCELLANEOUS

- None

RECONSTITUTION

Aseptic technique should be used during the reconstitution procedure. Don clean gloves. All components used in the reconstitution and administration of this product should be used as soon as possible after opening their sterile containers to minimize unnecessary exposure to the atmosphere. BeneFIX is administered by intravenous (IV) infusion after reconstitution with the supplied diluent (0.234% sodium chloride diluent).

1. If refrigerated, allow the vial of lyophilized BeneFIX and the pre-filled diluent syringe to reach room temperature.

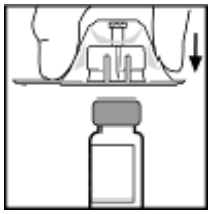
2. Remove the plastic flip-top cap from the BeneFIX vial to expose the central portions of the rubber stopper.

CLASSIFICATION	ALERTS
Recombinant Coagulation Factor IX Product. Standard Half-life	None

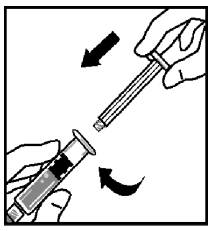
3. Wipe the top of the vial with an alcohol swab, or another antiseptic solution, and allow to dry. After cleaning, do not touch the rubber stopper with your hand or allow it to touch any surface.

4. Peel back the cover from the clear plastic vial adapter package. Do not remove the adapter from the package.

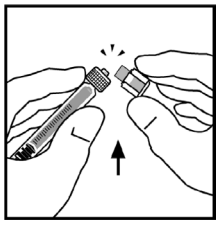
5. Place the vial on a flat surface. While holding the adapter in the package, place the vial adapter over the vial. Press down firmly on the package until the adapter snaps into place on top of the vial, with the adapter spike penetrating the vial stopper. Leave the adapter package in place.



6. Grasp the plunger rod as shown in the diagram. Avoid contact with the shaft of the plunger rod. Attach the threaded end of the plunger rod to the diluent syringe plunger by pushing and turning firmly.

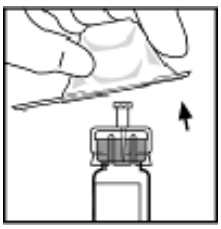


7. Remove the tamper-resistant, plastic-tip cap from the diluent syringe by bending the cap up and down to break the perforation. Do not touch the inside of the cap or the syringe tip. The cap may need to be replaced, so place the cap on its side on a clean surface in a spot where it would be least likely to become environmentally contaminated.

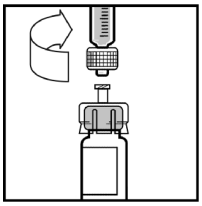


CLASSIFICATION	ALERTS
Recombinant Coagulation Factor IX Product. Standard Half-life	None

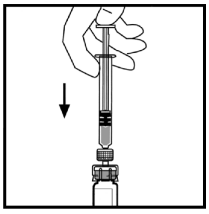
8. Lift the package away from the adapter and discard the package.



9. With the vial on a flat surface, connect the diluent syringe to the vial adapter by inserting the tip of the syringe into the adapter opening while firmly pushing and turning the syringe clockwise until the connection is secured.



10. Slowly depress the plunger rod to inject all the diluent into the BeneFIX vial.



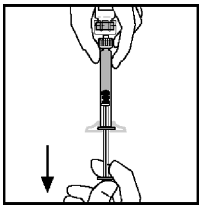
11. With the syringe still connected to the adapter, gently swirl the contents of the vial until the powder is dissolved. Inspect the final solution for specks before administration. The solution should appear clear and colorless.

Note: If you use more than one vial of BeneFIX per infusion, reconstitute each vial by following the previous instructions.

12. Ensuring that the syringe plunger rod is still fully depressed, invert the vial. Slowly draw the solution into the syringe.

If multiple vials are being used, all vials can be drawn up into the same syringe then administered.

13. Detach the syringe from the vial adapter by gently pulling and turning the syringe counterclockwise. Discard the vial with the adapter attached.



TRANSFUSION MEDICINE SERVICES

CLASSIFICATION	ALERTS
Recombinant Coagulation Factor IX Product. Standard Half-life	None

REFERENCES

- CL-BP-030, IWK-625 Blood Component and Blood Product Administration – Policy and Procedure
- Benefix product monograph. Found at https://www.pfizer.ca/en/our-products