Alprolix

TRANSFUSION MEDICINE SERVICES

CLASSIFICATION	ALERTS
Recombinant Coagulation Factor IX Product, Extended Half-life	None

PREPARATION and ADMINISTRATION

Alprolix is a recombinant factor IX product that does not contain human plasma therefore blood consent is not required.

Reconstitution

Diluent: sterile water for injection

See pages 3-6 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 determined 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 in adults and children with hemophilia A for:

- Prophylactic treatment to prevent or reduce the frequency of bleeding episodes
- The control and prevention of bleeding episodes
- Perioperative management

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ADVERSE EFFECTS

The most common adverse reactions in previously treated patients were headache, oral paresthesia, and obstructive uropathy. In previously untreated patients, injection site sensitivity and hypersensitivity occurred.

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.

- 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

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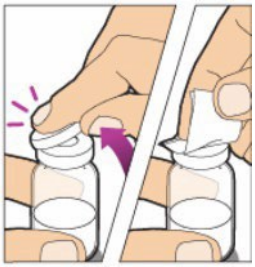
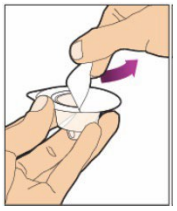
RECONSTITUTION

Use aseptic technique and a flat work surface during the reconstitution procedure. Put on clean gloves.

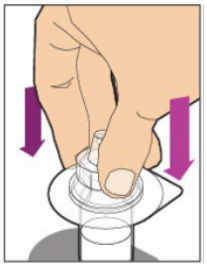
Remove the plastic cap from the Alprolix vial and wipe the rubber stopper of the vial with an alcohol wipe. Allow the rubber stopper to dry. After cleaning, do not touch the rubber stopper with your hand or allow it to touch any surface.

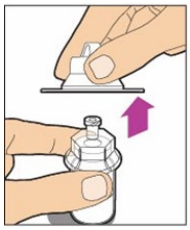




Completely remove the backing from the vial adapter package by peeling back the lid. Do not remove the vial adapter from the package or touch the inside of the package of the adapter.

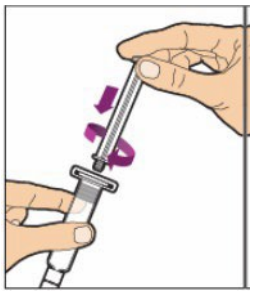
Keep the vial on a flat surface. Hold the vial adapter package with one hand and using the other hand, place the vial adapter over the vial. Place the adapter spike directly above the centre of the rubber stopper. Push the vial adapter straight down until the adapter spike punctures the centre of the vial stopper and is fully inserted.





Lift the package cover away from the vial adapter and discard the cover.

Take the plunger rod and syringe out of the package. Hold the plunger rod at the circular disk. Place the tip of the plunger rod into the end of the syringe. Turn clockwise until it is securely attached. Only use the diluent syringe provided in the Alprolix package.



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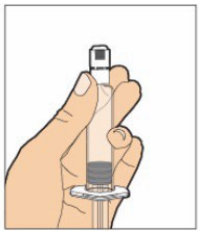
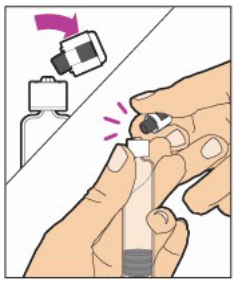
Reconstituting the injection

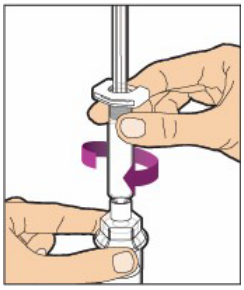
With one hand, hold the diluent syringe by the ridged part right under the cap, with the cap pointing up. Do not use if the cap has been removed or is not securely attached.

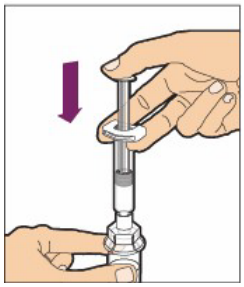




With your other hand, grasp the cap and bend it at a 90° angle until it snaps off. After the cap snaps off, you will see the glass tip of the syringe. Do not touch the glass tip of the syringe or inside of the cap.

Be sure the vial is sitting on a flat surface. Insert the tip of the syringe into the adapter opening. Turn the syringe clockwise until it is securely attached to the adapter.





Slowly depress the plunger rod to inject all of the diluent into the vial. The plunger rod may rise slightly after this process. This is normal.

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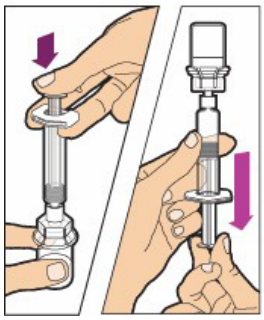
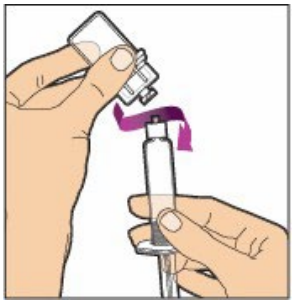
With the syringe still connected to the adapter, gently swirl the vial until the product is completely dissolved. The final solution should be clear to slightly opalescent and colourless. Do not shake. Do not use the reconstituted Alprolix if it contains visible particles or is cloudy.



Make sure the plunger rod is completely depressed. Turn the vial upside-down. Slowly pull on the plunger rod to draw the solution into the syringe. Be careful not to pull the plunger rod completely out of the syringe.

Gently unscrew the syringe from the vial adapter and dispose of the vial with the adapter still attached. Do not touch the syringe tip or the inside of the cap.



Alprolix is now ready to be connected to your infusion tubing set. Use as soon as possible, but no later than 3 hours after reconstitution.

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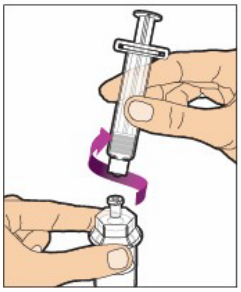
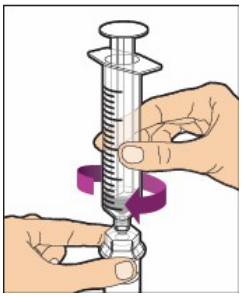
Pooling Products

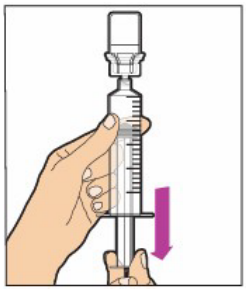
If you are using two or more vials of Alprolix and the bottles have the same Lot numbers, you can follow these pooling steps. Be sure to leave the vial adapter attached to the vial, as you will need it for attaching a large luer lock syringe. Do not detach the diluent syringe or the large luer syringe until you are ready to attach the large luer lock syringe to the next vial (with vial adapter attached).



Remove the diluent syringe from the vial adapter by turning it counterclockwise until it is completely detached.



Attach a separate large luer lock syringe by turning clockwise until it is securely attached.



Slowly pull on the plunger rod to draw the solution into the syringe. Repeat this pooling procedure with each vial you will be using. Once you have pooled the required dose, proceed to administration using the large luer lock syringe.

REFERENCES

- CL-BP-030, IWK-625 Blood Component and Blood Product Administration – Policy and Procedure
- Alprolix product monograph. Found at https://www.sanofi.ca/en/products-and-resources/prescription-products