

## TRANSFUSION MEDICINE SERVICES

<b>CLASSIFICATION</b> Recombinant Coagulation Factor VIII Product	<b>ALERTS</b> None
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### PREPARATION and ADMINISTRATION

Adynovate is a recombinant factor VIII product and does not contain human plasma therefore a blood consent is not required.

#### Reconstitution

Diluent: sterile water for injection

See pages 3–4 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
<b>IV Direct is the recommended route of administration.</b> 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 as reconstituted solution over <u>5</u> minutes or less as patient tolerates. If no indwelling IV, use the butterfly and supplies provided in the box.	<b>IV Bag (large volume pump)</b>	<b>IV Bag (large volume pump)</b>
	Not Recommended	Not applicable
	<b>Syringe (syringe pump)</b>	<b>Syringe (syringe pump)</b>
	Not Recommended	Not applicable

### Requirements and Monitoring

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

Document all vitals taken.

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

### ADVERSE EFFECTS

The most common adverse drug reactions reported in the clinical trials were headache, diarrhea, dizziness, nausea, and rash.

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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.  
 (Paediatric) 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.

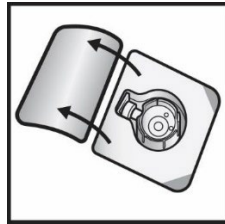
### RECONSTITUTION

1. Use aseptic technique and a flat work surface during the reconstitution. Allow the vials to reach room temperature before use. Put on clean gloves.
2. Remove plastic caps from the ADYNOVATE and diluent vials.
3. Cleanse rubber stoppers with an alcohol wipe and allow drying prior to use.

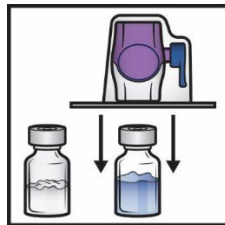
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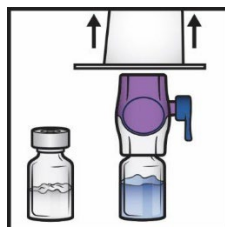
4. Open the BAXJECT II Hi-Flow device package by peeling away the lid, without touching the inside. Do not remove the device from the package.



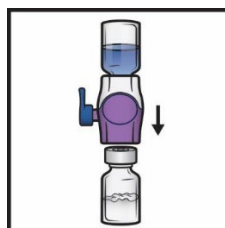
5. Turn the package over. Press straight down to fully insert the clear plastic spike through the diluent vial stopper.



6. Grip the BAXJECT II Hi-Flow package at its edge and pull the package off the device. Do not remove the blue cap from the BAXJECT II Hi-Flow device. Do not touch the exposed purple plastic spike.



7. Turn the system over so that the diluent vial is on top. Quickly insert the purple plastic spike fully into the ADYNOVATE vial stopper by pushing straight down. The vacuum will draw the diluent into the ADYNOVATE vial.



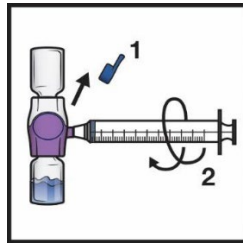
8. Swirl gently until ADYNOVATE is completely dissolved.

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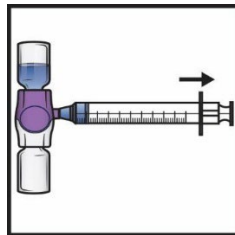
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### Administration Steps:

1. Remove the blue cap from the BAXJECT II Hi-Flow device. Connect the syringe to the BAXJECT II Hi-Flow device. Use of a plastic Luer-lock syringe is recommended. Do NOT inject air.



2. Turn the system upside down (ADYNOVATE vial now on top). Draw the factor concentrate into the syringe by pulling the plunger back slowly.



3. Disconnect the syringe; attach a suitable needle and inject intravenously as instructed under Administration by Bolus Infusion. If a patient is to receive more than one vial of ADYNOVATE, the contents of multiple vials may be drawn into the same syringe. Note: A BAXJECT II Hi-Flow device is required to reconstitute each vial of ADYNOVATE.

## REFERENCES

- [CL-BP-030, IWK-625 Blood Component and Blood Product Administration – Policy and Procedure](#)
- Adynovate product monograph. Found at <https://www.takeda.com/en-ca/what-we-do/our-medicines/>