Alberta Health Services

This document applies to all Covenant and AHS sites.

ADYNOVATE

Class: *Manufactured recombinant Anti-hemophilic product*

OTHER NAMES: anti-hemophilic factor (recombinant) PEGylated, PEGylated Factor VIII

Company: Shire Pharma Canada ULC

	INTRAVENOUS			OTHER		
ROUTES	**DIRECT IV**	**IV Infusion**	**Continuous Infusion**	**SC**	**IM**	**OTHER**
Acceptable Routes*	Yes**	No	No	No	No	N/A

*** Professionals performing these restricted activities have received authorization from their regulatory college and have the knowledge and skill to perform the skill competently.**

**** Transfusion of Blood Components and Products Learning Module Section Three: Direct IV Administration of Blood Products. RNs may administer direct IV blood products. Not to be confused with medication administration**

DESCRIPTION OF PRODUCT:

- ADYNOVATE is a sterile, non-pyrogenic, preservative-free, lyophilized, white to off-white powdered concentrate of fully recombinant human coagulation factor VIII for intravenous administration.
- ADYNOVATE is a full-length form of ADVATE molecule that is covalently conjugated with a PEG (polyethylene glycol) reagent. PEGylation is done to increase plasma half-life of the product.
- Available in dose sizes of 250, 500, 1000 and 2000 IU.
- The diluent is 5mL Sterile Water for Injection.

AVAILABILITY:

- Supplied by CBS
- Contact your local laboratory/transfusion service regarding stock availability on site.

INDICATIONS FOR USE:

- Indicated in adults and children with hemophilia A (congenital factor VIII deficiency) for:
  - Routine prophylactic treatment to prevent or reduce the frequency of bleeding episodes
  - Control and prevention of bleeding episodes (e.g. in trauma or procedures with increased risk of bleeding).
  - Perioperative management (surgical prophylaxis)

CONTRAINDICATIONS:

- Patients with von Willebrand Disease (ADYNOVATE does not contain von Willebrand Factor).
- Known hypersensitivity to the product, the parent molecule ADVATE, mouse or hamster proteins or any of the constituents in the formulation of ADYNOVATE (Tris, calcium chloride, mannitol, sodium chloride, trehalose, glutathione, histidine, and/or polysorbate 80).

WARNINGS:

- Development of activity-neutralizing antibodies has been detected in patients receiving factor VIII-containing products. If expected plasma factor VIII activity levels are not attained, or if bleeding is not controlled with an appropriate dose, an assay that measures factor VIII inhibitor concentration should be performed.
- Anaphylaxis and anaphylactoid reactions are possible.
- PEG exposure levels resulting from ADYNOVATE therapy are very low. Based upon available experimental data, there is also a lack of evidence supporting the potential for accumulation of the specific PEG (20kDA) used in the pegylation of ADYNOVATE. The potential for PEG accumulation with ADYNOVATE is therefore considered to be low.

DOSE (Refer to Product Insert):

1 IU of ADYNOVATE per kg body weight is expected to increase, on average, the circulating level of factor VIII by 2%.

- Dosage must be individualized to the severity of factor VIII deficiency, location and extent of bleeding, presence of inhibitors, Factor VIII level desired, and the patient's clinical condition.
- The required dosage is calculated using the following formula:

Required units=body weight (kg) x desired factor VIII rise (IU/dl or % of normal) x 0.5 (IU/kg per IU/dl)

**** Consult with Hematologist or the bleeding disorder clinic ****

ADMINISTRATION:

Confirm written (signed) consent has been obtained and documented prior to requesting blood component from lab/transfusion service where possible.

Pre-Infusion: Ensure recent patient weight is on file and pertinent labs are available. Perform the appropriate pre-transfusion checks per protocol.

Access: ADYNOVATE can be given via CVC, PICC, Port-a-Cath®, or peripheral IV line.

Reconstitution Supplies:

- ADYNOVATE, lyophilized in single dose vial
- Diluent (5 mL Sterile Water for Injection)
- BAXJECT II Hi-Flow device

} Contained in box

Administration Supplies:

- **For direct IV administration:**
  - Sterile infusion set (provided in kit), if no established IV access

Reconstitution: Refer to reconstitution steps with vial adapter at:
http://www.albertahealthservices.ca/assets/wf/lab/wf-lab-clin-tm-adynovate-reconst.pdf

Administration:

- Give as soon as possible, but within a maximum of 3 hrs of reconstitution.
- Do not refrigerate after reconstitution.
- **DO NOT** mix with other drugs or IV solutions.

Administration rate:

- May be given over a period of 5 min or less, not to exceed 10 mL/minute.
- Administration rate should be determined by the ordering physician, local bleeding disorders clinic, and as tolerated by the patient.

POTENTIAL HAZARDS WITH PARENTERAL ADMINISTRATION:

- Potential adverse events related to a blood product transfusion range in severity from minor with no sequelae to life-threatening.
- All adverse events occurring during a transfusion should be evaluated to determine whether or not the transfusion can be safely continued/restarted.
- All adverse events suspected to be related to a product transfusion (whether during or after a transfusion) should be reported to your local transfusion service.

Side Effects - Flushing - Headache - Nausea - Itching and redness at the venipuncture site	→ **Action** Slow rate of infusion
Potential Allergic Reaction - Stuffy nose - Hives/severe itching - Cough - Chest pain - Wheezing - Facial swelling	→ **Action** **STOP** infusion **IMMEDIATELY** and contact physician

NURSING IMPLICATIONS:

Patient Monitoring:

- Vital Signs: Pre-administration**,** on completion of dose, and as patient condition requires (see administration rate).

Patients receiving blood product transfusions must be observed closely for signs of any unexpected or untoward reactions. These reactions may occur during or after the infusion of blood or blood products. For follow up to a transfusion reaction see: http://www.albertahealthservices.ca/lab/page4240.aspx Notify the transfusion service as soon as possible that an adverse reaction has occurred.

Documentation:

- Ensure documentation is completed as per the AHS *Transfusion of Blood Components and Products* procedure.
- Assessment of patient tolerability should be documented in appropriate flow chart or clinical record (electronic or paper) as required.

STORAGE & STABILITY OF PRODUCT:

- Stored at 2-8°C. **Do not freeze.**
- Protect from light.
- May be stored for a single period of up to 3 months at room temperature (up to 30 ºC) Do not exceed expiry date. Do not return to refrigerated storage.
- Expiration date is indicated on bottle and packaging.
- Administer within 3 hours of reconstitution (reconstituted product can be stored at room temperature until administered).

COMMENTS:

Date Effective: 13 Sept 2019
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Approved By: APL Transfusion Medicine Discipline Council
Document Number: PTMGNR00057
For questions or comments about this document, please contact Transfusion.SafetyTeam@ahs.ca

REFERENCES

ADYNOVATE product monograph SCN 211971

LINK to WEBSITE for PRESCRIBING INFORMATION:

https://www.shirecanada.com