ALBERTA PRECISION LABORATORIES
Leaders in Laboratory Medicine

Factor VII « Takeda »

APPLICABILITY: This document applies to all APL, AHS, Covenant Health, and all other health care professionals involved in the transfusion of blood components and products in Alberta.	***Other Names:*** *Factor VII concentrate (human)* ***Company:*** *Takeda* ***Class:*** *Manufactured blood product, derived from human plasma*

In the event of discrepancy between APL Monograph and Manufacturer's documentation or patient resources, the APL Monograph will take precedence.

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

* Administration of blood components and blood products is a restricted activity. For specific conditions that apply to a profession's authorization to administer blood components and blood products, consult the applicable discipline-specific regulation under the Health Professions Act (Alberta). Health care professionals with this authorization require the applicable education, training and competency.

** Direct IV administration of blood products may be performed by health care professionals that have authorization of administration of blood products within their scope of practice.

DESCRIPTION:

- Factor VII "Takeda" is a vitamin K-dependent coagulation factor prepared from human plasma.
- Factor VII "Takeda" undergoes viral inactivation and/or removal, which are effective against enveloped viruses (e.g. HIV, HBV, HCV), and for the non-enveloped virus HAV. It may not be effective against some non-enveloped viruses such as parvovirus B19.
- Available in 600 IU single-dose vial of sterile, preservative-free lyophilized powder.
- After reconstitution with the full volume of supplied diluent (10 mL sterile water for injection), human factor VII concentration is 60 IU/mL.
- Also contains: sodium chloride, sodium citrate, and heparin sodium.
- The lyophilized powder is white or slightly colored, and the reconstituted solution should be clear or slightly opalescent and colorless to slightly yellow.
- The approximate half-life of factor VII is 3 – 5 hours.

AVAILABILITY

- Factor VII "Takeda" is an **unlicensed product** in Canada. Patient-specific requests must be approved by Health Canada's Special Access Programme (SAP). Authorized prescriber must contact the Transfusion Medicine physician on-call before placing any orders.

INDICATIONS FOR USE:

- Prevention and treatment of bleeding disorders due to congenital factor VII deficiency and for previous bleeding events and a residual level of factor VII:C lower than 25% of the normal value (0.25 IU/mL).

CONTRAINDICATIONS:

- Patients with hypersensitivities to human coagulation factor VII or any of the other ingredients of Factor VII "Takeda."
- Patients with high risk of thrombosis or disseminated intravascular coagulation (DIC).
- Patients allergic to heparin or with a history of heparin-induced thrombocytopenia (HIT).
- Patients with hemophilia with inhibitors.

MANUFACTURER'S WARNINGS:

- Patients should be monitored for signs and symptoms of thrombosis or DIC.
- Development of circulating antibodies (inhibitors) to factor VII may occur with replacement therapy.
- Anaphylaxis and anaphylactoid reactions are possible.
- Not recommended for children less than 6 years old due to limited data.

DOSE:

- Dose to be determined by the most responsible health practitioner (MRHP) after consultation with Hematologist or bleeding disorders clinic and may be different than the manufacturer's recommendations below.
    - Dose frequency: 6 – 8h generally sufficient if intermittent administration.
- Refer to patient's care plan or Factor First card, if available.
- Dosage must be individualized to the severity of factor VII deficiency, location and extent of bleeding, presence of inhibitors, FVII levels desired, and the patient's clinical condition.
- One IU factor VII per kg body weight is expected to increase the plasma factor VII activity by about 1.9% of normal activity.

Manufacturer Recommendations:

Degree of hemorrhage/Type of surgical procedure	Required Factor VII plasma level in % or IU/dl	Required Factor VII plasma level (IU/mL)	Frequency of doses (h) / Duration of therapy (days)
Minor hemorrhage	10 – 20	0.10 – 0.20	Single dose
Severe hemorrhage	25 (trough) – 40 (peak)	0.25 (trough) – 0.40 (peak)	8 – 10 days, or until complete healing
Minor surgical interventions	20 - 30	0.20 – 0.30	Single dose before surgery, or - if estimated bleeding risk is more pronounced, until cessation of bleeding
Major surgical interventions	Pre-op: >50 Then, 25 (trough) – 45 (peak)	Pre-op: >50 Then, 25 (trough) – 45 (peak)	8 – 10 days, or until complete healing

ADMINISTRATION:

Confirm signed consent has been obtained and documented prior to requesting blood components or products (human-source) 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 transfusion policy and procedure.

Access:

- Peripheral IV or central venous access site.

Compatible IV solutions:

- Do not mix with other medicinal products.

Reconstitution Supplies:

- Factor VII "Takeda" lyophilized powder
- 1 vial of diluent (10mL sterile water for injection)
- Double-ended transfer needle
- Aeration needle
- Filter needle

} Included with product

- Sterile plastic luer lock syringe (large enough to contain dose) (not included with product)
- Alcohol swabs (not included with product)

Administration Supplies:

- Winged (needle) infusion set (if needed)
- Alcohol swabs (not included with product)

Reconstitution Instructions:

- See double-ended transfer needle reconstitution instructions.
- Use the aeration needle after reconstitution if needed, to collapse any foam. Discard aeration needle after use.
- Use the filter needle to draw up the reconstituted solution for administration, then discard the filter needle.
- Use within 3h of reconstitution.

Administration Instructions:

- Administer via direct IV.
- Administration rate: maximum 2 mL/min.

NURSING IMPLICATIONS:

Patient Monitoring:

- Vital Signs: Pre-administration**,** on completion of dose, and as patient condition requires.
- If the patient has experienced previous adverse reaction to product transfusion, or this is the first transfusion of product for patient, monitor for 30-60 minutes post.

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 Transfusion Reactions | Alberta Health Services. Notify the transfusion service as soon as possible that an adverse reaction has occurred.

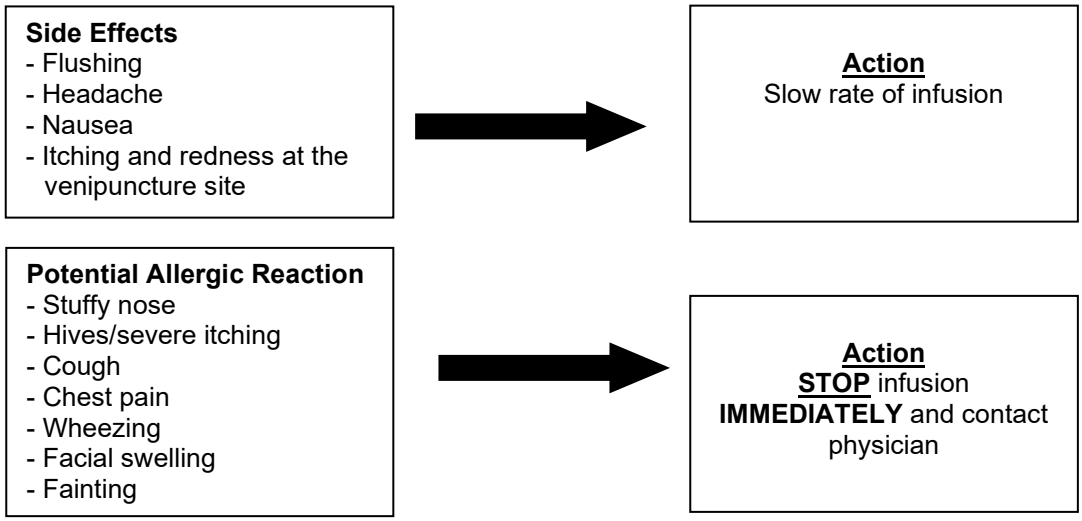
Documentation:

- Ensure documentation is completed as per the AHS Transfusion of Blood Components and Products Policy
- Start and stop time of infusion and assessment of patient tolerability should be documented in appropriate flow chart or clinical record (electronic or paper).
- Document vital signs as required in the appropriate flow chart or clinical record (electronic or paper).
- Provide patient notification of transfusion documentation where required.

POTENTIAL HAZARDS WITH PARENTERAL ADMINISTRATION:

Adverse Events

- 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) must be reported to your local transfusion service.
- The most common adverse reactions observed are: flushing, rash, fever, chest pain, and generally feeling unwell.



STORAGE & STABILITY:

- Store between 2°C - 8°C.
- Do not freeze.
- Protect from light.

Contact Information

Approved By: APL Transfusion Medicine Discipline Council

For questions or comments regarding this document please contact: Transfusion.SafetyTeam@aplabs.ca

REFERENCES:

Package leaflet: Factor VII "Takeda" 600 IU powder and solvent for solution for injection.