ALBERTA PRECISION LABORATORIES
Leaders in Laboratory Medicine

Immunine® VH
Factor IX Concentrate (Human)

APPLICABILITY: This document applies to APL, AHS, Covenant Health, and all other health care professionals involved in the transfusion of blood components and products in Alberta.	***OTHER NAMES:*** *Factor IX Concentrate, FIX* ***Company:*** *Takeda Canada* ***Class:*** *Manufactured blood product, derived from human plasma*

	INTRAVENOUS			OTHER		
ROUTES	**DIRECT IV**	**Intermittent Infusion**	**Continuous Infusion**	**SC**	**IM**	**OTHER**
Acceptable Routes*	Yes**	Yes	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:

- Immunine® is a purified, sterile, freeze-dried concentrate of human blood coagulation factor IX prepared from large pools of human plasma.
- Pathogen inactivation steps include vapor heat treatment.
- Each Immunine® vial contains the labeled amount (480-720 IU) of concentrated human factor IX.
- Lyophilized powder is white or pale yellow. Solution is clear or slightly opalescent.
- Available in 500IU single-dose vials.
- Vials are reconstituted with sterile water for injection to a concentration of 96-144 IU/mL.
- Also contains Factor II, VII, and X (less than 0.02 IU per IU of Factor IX), sodium chloride, sodium citrate, Tween 80, and heparin (less than 0.1 IU per mL).
- Preservative-free.
- Latex-free.

AVAILABILITY:

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

INDICATIONS:

- Treatment and prophylaxis of bleeding episodes in patients with congenital or acquired Factor IX deficiency.

CONTRAINDICATIONS:

- Patients who are hypersensitive to Factor IX, or any ingredient in the formulation or component of the container.
- Known allergy to heparin or history of heparin induced thrombocytopenia.
- Disseminated intravascular coagulation (DIC) and/or hyperfibrinolysis.

WARNINGS:

- Caution should be exercised in patients with a risk of thrombosis (e.g. history of severe liver disease, thrombophilia, or a tentative or definitive diagnosis of angina pectoris, coronary heart disease, or myocardial infarction).
- Replacement therapy with Immunine® VH may lead to the development of circulating antibodies which inhibit Factor IX.

DOSE (Refer to Product Insert)**:**

- Dose to be determined by the most responsible health practitioner (MRHP) only after consult with Hematologist or bleeding disorders clinic.
- Dosage and duration of treatment depend on the severity of the Factor IX deficiency, location and extent of bleeding, presence of inhibitors, Factor IX level desired, and the patient's clinical condition.
- One IU of Immunine® per kg body weight is expected to increase the factor IX plasma level by approximately 0.8%.
- Generally given every 24 hours based on the biological half-life of Factor IX.
- **Surgical prophylaxis:**
  - Initial dose should be administered 1 hour prior to surgery.
  - For major surgical interventions, 12-hour treatment intervals should be maintained during the first post-operative days.
- **On-demand treatment:**
  - Refer to patient's care plan for Factor First card, if available.
  - If neither are available, consult with bleeding disorders clinic or transfusion medicine physician.

ADMINISTRATION:

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

Pre-Infusion:

- Ensure recent patient weight and height is on file.
- Ensure pertinent labs are available as required.
- Ensure any ordered pre-medications have been given (antihistamines, antipyretics prn).
- Perform pre-transfusion checks per AHS Transfusion of Blood Component and Blood Products Policy.
- Report any new onset acute illness to the authorized prescriber prior to commencing infusion.

Access: Immunine® can be given via peripheral or central venous access site.

Reconstitution Supplies:

- Immunine® product (lyophilized powder)
- 5mL Sterile water for injection (included with product)
- Double-ended transfer needle (included with product)
- Filter needle (included with product)
- Antiseptic swabs (not included with product)

Reconstitution:

- Bring Immunine® to room temperature before reconstitution.
- See Double-Ended Transfer Needle Reconstitution Instructions.
- Do not refrigerate after reconstitution.

Compatible IV Solutions:

- Immunine® should not be mixed with other medicinal products or solutions.
- Normal saline can be used to flush the line.

Administration Supplies:

- Sterile plastic luer lock syringe (large enough to contain dose)
- Filter needle (included with product)
- IV administration set (included with product)
- IV pump (if required)

Administration Set: Immunine® should be given using the administration set provided with the product.

Administration:

- Administer immediately after reconstitution.
- Visually inspect the product prior to administration. Do not use products that are cloudy or contain particulates.
- Withdraw the reconstituted solution into the syringe from the vial using the included filter needle.
- Remove and discard the filter needle from the syringe.
- **Administration Rate:**
  - Administration rate should be specified by the MRHP after patient assessment.
  - Maximum rate is 2 mL/minute

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) must be reported to your local transfusion service.
- The most common reactions to Immunine® VH are throat irritation, oropharyngeal pain, cough, rash, pruritus, pyrexia, and formation of inhibitors.

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 - Fainting	→	**Action:** **STOP** infusion **IMMEDIATELY** and contact physician

NURSING IMPLICATIONS:

Patient Monitoring:

- Vital Signs: Pre-administration**,** on completion of dose, and as patient condition requires.
- If the patient has experienced a previous adverse reaction to product transfusion, or this is the first transfusion of the product for the 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 instructions to a transfusion reaction, go to http://www.albertahealthservices.ca/lab/page4240.aspx

Documentation:

- Ensure documentation is completed as per the *AHS Transfusion of Blood Components and Blood 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.

LABORATORY MONITORING

- Regular determinations of the patient's factor IX plasma level are necessary for monitoring the course of therapy and calculation of appropriate maintenance doses.
- Patient should be monitored for the development of factor IX inhibitors. If the expected factor IX activity plasma levels are not attained, or if bleeding is not controlled with an appropriate dose, an assay should be performed to determine if a factor IX inhibitor is present.

STORAGE & STABILITY:

- Store at 2-8°C until expiry.
- May be stored at room temperature (not to exceed 25°C) for a period of up to 3 months within its shelf life. Product expires after 3 months at room temperature. Do not return to refrigeration once removed.
- Do not refrigerate reconstituted solution.

CONTACT INFORMATION:

Approved By: APL Transfusion Medicine Discipline Council
For questions or comments please contact: Transfusion.SafetyTeam@aplabs.ca

REFERENCES

Takeda Canada Inc. February 2021. Immunine VH product monograph. Submission Control No 242680. [Accessed 13Jan22]. https://www.takeda.com/493a93/siteassets/en-ca/home/what-we-do/our-medicines/product-monographs/immunine-vh/immunine-vh-pm-en.pdf

Takeda Medical Information. 29Mar22. Letter Re: medical information request, ref: 00313489.

PS-59 AHS Transfusion of Blood Components and Blood Products Policy.