Alberta Health Services

This document applies to all Covenant and AHS sites.

# Panhematin®

***Class:*** *Manufactured blood product (human)*

**OTHER NAMES:**
*Hemin, Hematin*

| | INTRAVENOUS | | | OTHER | | |
|---|---|---|---|---|---|---|
| **ROUTES** | **DIRECT IV** | **Intermittent Infusion** | **Continuous Infusion** | **SC** | **IM** | **OTHER** |
| **Acceptable Routes*** | No | Yes | 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.**

**DESCRIPTION OF PRODUCT:**

- Panhematin® (hemin for injection) is an enzyme inhibitor prepared from large pools of human red blood cells.
- Viral inactivation and/or removal processes include: solvent detergent method, heat and acid treatment.
- After reconstitution, each 48 mL vial of Panhematin® contains the equivalent of approximately 268 mg of hematin (5.4 mg/mL).
- Each vial contains the equivalent of 268 mg hemin, 240 mg sodium carbonate, and 335 mg sorbitol.
- Sterile, preservative-free, black lyophilized powder in single dose vials.
- Vial stopper contains natural rubber latex.
- May contain hydrochloric acid (for pH adjustment).

**AVAILABILITY:**

- Panhematin is not routinely stocked in Alberta hospitals. Patient-specific requests must be approved. Consult your transfusion service/laboratory for requesting information.
- Supplied by Canadian Blood Services.
- Contact your local laboratory / transfusion service regarding availability.

**INDICATIONS FOR USE:**

- Patients will be considered for approval for Panhematin® if:
  - The patient suffers recurrent attacks of acute intermittent porphyria.
  - Initial carbohydrate therapy is known or suspected to be inadequate.
- Clinical benefit from Panhematin® depends on prompt administration. For moderate to severe attacks, immediate hemin treatment is recommended. Symptoms of severe attacks are severe or prolonged pain, persistent vomiting, hyponatremia, convulsion, psychosis, and neuropathy.
- For mild porphyric attacks (mild pain, no vomiting, no paralysis, no hyponatremia, no seizures), a trial of glucose therapy is recommended while awaiting hemin treatment or if hemin is unavailable.
- Before Panhematin® therapy is begun, the presence of acute porphyria must be diagnosed using the following criteria:
  - Presence of clinical symptoms suggestive of acute porphyric attack
  - Genetically proven porphyria.
  - Quantitative measurement of porphobilinogen (PBG) in urine.
- Effectiveness may be demonstrated by clinical improvement, or by a decrease in one or more of the following compounds in urine: ALA - δ-aminolevulinic acid, PBG – porphobilinogen, Uroporphyrin, Coproporphyrin

**CONTRAINDICATIONS / CAUTIONS:**

**Contraindications**

- Patients who are hypersensitive (allergic) to this drug or any ingredient in the formulation or container (see product monograph for complete listing).
- Panhematin® is not effective in repairing neuronal damage caused by previous attacks of porphyria.
- Not authorized by Health Canada for use in pediatrics < 16 years of age.

**Cautions**

- The vial stopper **contains latex.**
- Before administering Panhematin®, consider an appropriate period of carbohydrate loading (ie. 400g glucose/day for 1 to 2 days).
- Panhematin® should be infused in a large arm vein or central venous catheter to minimize the risk of phlebitis.
- Panhematin® may cause transient, mild anticoagulant effects.
- Panhematin® may cause increased serum iron and ferritin levels. Iron chelation therapy may be required for patients who receive multiple administrations.
- Recommended dosage guidelines should be strictly followed. Reversible renal shutdown has been observed in a case where an excessive hematin dose (12.2 mg/kg) was administered in a single infusion.
- Insufficient data exists on the safety, effectiveness, and dosing in pediatric (<16 years), pregnant, breastfeeding, and geriatric patient groups

**DOSE:**

- Consult with a hematologist or a physician experienced in the management of porphyrias.
- The standard dose is 2.3 to 3.1 mg/kg/day. Do not repeat more than every 12 hours. Do not exceed 4.6mg/kg in any 24 hour period.
- Recommended dose is 0.8 – 3.1 mg/kg/day for 3 – 14 days.

**ADMINISTRATION:**

***Ensure patient consent has been obtained prior to requesting blood product 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 nursing protocol.
- Consider giving 50mL 50% dextrose through the IV line as bolus prior to Panhematin
- Refer to physician orders for patient-specific reconstitution and administration instructions, if applicable.

**Access:** For intravenous infusion only. A large arm vein or central venous catheter is recommended to minimize the risk of phlebitis.

**Reconstitution Supplies:**

- Vial of Panhematin® lyophilized powder
- 48mL Sterile Water for Injection, USP (not supplied in packaging)
- Sterile plastic Luer lock syringe
- Alcohol swabs
- Blunt transfer needle

**Administration Supplies:**

- Vented IV administration set with 0.45 micron or smaller filter
- IV pump

**Reconstitution:**

- Reconstitute immediately before use. Panhematin® contains no preservative and undergoes rapid chemical decomposition in solution.
- Using aseptic technique, use a blunt transfer needle, or other appropriate transfer device and syringe to transfer 48mL of Sterile Water for Injection into the product vial.
- Shake the vial well for a period of 2 to 3 minutes.

**Administration**

- A large arm vein or central venous catheter should be used to minimize the risk of phlebitis.
- Visually inspect for discoloration and particulate matter.
- Administration through a sterile 0.45 micron or smaller filter is recommended since reconstituted Panhematin® is not transparent and any undissolved particulate matter is difficult to see.
- Administer through a filtered IV set.
- After infusion, flush the vein with 100mL of fast-flowing 0.9% NaCl.
- Vials are single-use only. Any product remaining in the vial should be discarded.

**Additional Notes**

- In hospital/facility storage of Hemlibra must be in a Transfusion Service approved location. Product stored by the patient for home use must be in compliance with the manufacturer's recommendations.
- Discard any unused portion immediately after it has been accessed

**Compatible Solutions:**

- Sterile Water for Injection

**Infusion Rate**

- Recommended infusion rate is 1mL/min. Infuse over a period of at least 30 minutes.

**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. Acute reactions need medical involvement.
- 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.
- Reversible renal shutdown has been observed in a case where an excessive hematin dose (12.2 mg/kg) was administered in a single infusion.
- The most common adverse reactions to Panhematin include headache, pyrexia, infusion site reactions, and phlebitis.

**NURSING IMPLICATIONS:**

**Patient Vital Signs and Monitoring**:

| | Pre-transfusion | At each rate increase (to assess tolerability) | Remainder of transfusion | Post-transfusion |
|---|---|---|---|---|
| Adults | Yes | Yes | On completion of dose | 20-30 min post, then PRN |

*Note: Vital signs/patient monitoring may be conducted more frequently as determined by clinical condition of patient.*

**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, click http://www.albertahealthservices.ca/4240.asp**

**Documentation:**

- The transfusion documentation should be double signed (where required) to indicate infusion
- Start and stop time of infusion and assessment of patient tolerability should also be documented in appropriate flow chart or clinical record (electronic or paper) as required
- Document vital signs as required in the appropriate flow chart or clinical record (electronic or paper)..
- Provide patient notification of transfusion documentation where required

**STORAGE & STABILITY of PRODUCT:**

- Store at 20 - 25$^{O}$C

**COMMENTS:**

Date Effective: 19 Dec 2019
Version 1.1
Approved By: APL Transfusion Medicine Discipline Council
Document Number: PTMGNR00066
*For questions or comments, please contact Transfusion.SafetyTeam@ahs.ca*

**REFERENCES:**

Panhematin® Product Monograph.
www.recordatirarediseases.com