Panhematin

TRANSFUSION MEDICINE SERVICES

OTHER NAMES	CLASSIFICATION	ALERTS
Hemin	Hemin for Injection	Made from processed human red blood cells

PREPARATION and ADMINISTRATION

Reconstitution

Diluent: sterile water (48 mL) for injection **Note:** Shake the vial well for a period of 2 to 3 minutes to aid dissolution.

See pages 3-4 for reconstitution steps -administer immediately after reconstitution.

PANHEMATIN may be administered directly from the vial. Since reconstituted product is not transparent, terminal filtration through a sterile 0.2 micron or smaller filter is recommended.

IV Direct	Intermittent Infusion	Continuous Infusion
Not applicable	**IV Bag (large volume pump)**	**IV Bag (large volume pump)**
	Infuse the dose over a period of at least 30 minutes via a separate line. After the infusion, flush the vein with 100 mL of NS.	Not applicable
	Syringe (syringe pump)	**Syringe (syringe pump)**
	Solution may be administered from a 60 mL syringe. Infuse the dose over a period of at least 30 minutes via a separate line. After the infusion, flush the vein with 100 mL of NS.	Not applicable

Requirements and Monitoring

Baseline vitals within 60 min before starting infusion. Check vital signs 15 minutes after initiation.

Inpatients should be observed for an adverse event for 24 hours post infusion. **Document all vitals taken**.

Blood pressure via cuff or arterial line
Temperature
Heart Rate
Respirations
Lung sounds in non-verbal, non-oriented or pediatric patients and patients with CHF or pulmonary dysfunction

Keep unopened back up bag of NS and standard IV tubing nearby for prompt response if an adverse event (AE) occurs.

INDICATIONS

Indicated for the amelioration of recurrent attacks of acute intermittent porphyria temporally related to the menstrual cycle in susceptible women, after initial carbohydrate therapy is known or suspected to be inadequate.

Limitations of Use:

- Before administering, consider an appropriate period of carbohydrate loading (i.e., 400 g glucose/day for 1 to 2 days) (see Dosage).
- Attacks of porphyria may progress to a point where irreversible neuronal damage has occurred. PANHEMATIN therapy is intended to prevent an attack from reaching the critical stage of neuronal degeneration, but is not effective in

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repairing neuronal damage.

- Based on the data submitted and reviewed by Health Canada, the safety and efficacy of PANHEMATIN in pediatric patients has not been established; therefore, Health Canada has not authorized an indication for pediatric use.

ADVERSE EFFECTS

Allergic-type hypersensitivity reactions including anaphylaxis have been reported and have manifested as pruritus, rash, urticaria, local site reactions, hives, facial swelling, dizziness, hypotension, nausea, chest discomfort, cough, dyspnea, wheezing, flushing, discomfort (generalized) and fatigue.

If an AE is suspected: stop the transfusion, disconnect and cap the blood tubing, initiate the backup line of NS 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 transfusion 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 transfusion is discontinued or completed.

DOSAGE

The standard dose in clinical practice is 2.3 to 3.1 mg/kg/day. In more severe cases this dose may be repeated no earlier than every 12 hours. Do not exceed 4.6 mg/kg of hematin in any 24 hour period. After reconstitution each mL of PANHEMATIN contains the equivalent of approximately 5.4 mg of hematin (see dosage calculation table below).

Dosage Calculation Table

1 mg hematin equivalent = 0.18 mL PANHEMATIN
2 mg hematin equivalent = 0.37 mL PANHEMATIN
3 mg hematin equivalent = 0.55 mL PANHEMATIN
4 mg hematin equivalent = 0.74 mL PANHEMATIN

COMPATIBILITY, STABILITY

- Compatible with NS
- Single use vials. Do not use past expiry date
- Do not dilute in any IV solutions
- Protect vials from light
- Do not store unused vials in refrigerator. Administer at room temperature

DOSAGE FORMS

- Supplied by Transfusion Medicine. (Blood Bank)

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MISCELLANEOUS

- The vial stopper of PANHEMATIN contains natural rubber latex, which may cause allergic reactions.
- Utilize a large arm vein or a central venous catheter for administration to minimize the risk of phlebitis.
- Elevated iron and serum ferritin may occur. Monitor iron and serum ferritin in patients receiving multiple administrations of PANHEMATIN.

RECONSTITUTION

PANHEMATIN must be reconstituted immediately before use, because it contains no preservative and undergoes rapid chemical decomposition in solution.

Supply List

1 Vial of PANHEMATIN® (hemin for injection)
1 Bottle Sterile Water for Injection, USP
1 60 mL syringe with 18-20 gauge needle
4 Alcohol wipes
1 Protective gloves
1 Infusion pump
1 Primary infusion set (including IV administration tubing with "Y" site)
1 250 mL IV bag of 0.9% Sodium Chloride for Injection, USP
1 Sterile 0.2-micron or smaller filter
1 IV tubing with vented spike, or vented spike adapter
1 Huber needle and injection cap
1 Saline flush syringe
1 IV bag label

1. Using aseptic technique, remove caps from Sterile Water for Injection, USP bottle and PANHEMATIN vial. Clean rubber stoppers* with alcohol wipes.

2. Using the 60 mL syringe, withdraw 48 mL Sterile Water for Injection frombottle.

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3. Inject the Sterile Water into the PANHEMATIN dispensing vial. Do not add other drug or chemical agent to a PANHEMATIN fluid admixture.

4. Immediately after adding diluent, shake the PANHEMATIN vial for 2–3 minutes to aid dissolution. Reconstituted PANHEMATIN is not transparent.

Administering PANHEMATIN® (hemin for injection)

Step 1 – Establish an IV Line

1. Protect patient's clothing with a towel or pad.
2. Use a large arm vein or central venous catheter to avoid the possibility of phlebitis.
3. Connect primary tubing to the 250 mL bag of 0.9% Sodium Chloride for Injection, USP, and prime.
4. Verify blood return and flush IV to verify patency, then attach the line.
5. Start the sodium chloride infusion at a "keep vein open" (KVO) rate.

Step 2 – Infuse PANHEMATIN® (hemin for injection)

1. Use a 0.2-micron filter with regular IV pump tubing, since undissolved particulate matter is difficult to see in PANHEMATIN. If the tubing is not vented, attach a vented spike adapter, and then insert the spike into the evacuated PANHEMATIN vial.
2. Prime the IV and filter system with PANHEMATIN. Attach IV line to the "Y" site on the primary infusion line, and stop the saline infusion.
3. Open the clamp on the IV tubing and begin infusion. The prescribed dose of PANHEMATIN should be infused over a

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period of at least 30 minutes.

4. After the full dose has been given, stop the infusion. Disconnect the PANHEMATIN at the "Y" site, and remove the vial and PANHEMATIN tubing. Rinse the vein with 100 mL 0.9% Sodium Chloride for Injection, USP. Discard any remaining PANHEMATIN solution.

REFERENCES

- CL-BP-030, IWK-625 Blood Component and Blood Product Administration – Policy and Procedure
- Panhematin product monograph. Found at https://www.recordatirarediseases.com/products