PANHEMATIN®
(HEMIN FOR INJECTION)
Dosing, preparation, and infusion instructions

About PANHEMATIN

PANHEMATIN is supplied as a sterile, lyophilized, black powder in single-dose dispensing vials containing 350 mg hemin, 240 mg sodium carbonate, and 335 mg sorbitol. When mixed as directed with Sterile Water for Injection, USP, each 48 mL provides the equivalent of approximately 336 mg hematin (7 mg/mL).

Prior to reconstitution, PANHEMATIN should be stored at room temperature (68°-77°F). PANHEMATIN contains no preservative, and it undergoes rapid chemical decomposition in solution. Therefore, PANHEMATIN should not be reconstituted until immediately before use.

INDICATIONS AND USAGE

PANHEMATIN is a hemin for injection 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. (See Limitations of Use on page 5 of this brochure.)

IMPORTANT SAFETY INFORMATION

PANHEMATIN is contraindicated in patients with known hypersensitivity to this drug.

Risk of Phlebitis: Phlebitis is possible. Utilize a large arm vein or a central venous catheter for administration to minimize the risk of phlebitis.

For more information, please see Important Safety Information on page 5 and accompanying full Prescribing Information.

Dosing PANHEMATIN® (hemin for injection)

PANHEMATIN should only be used by or in consultation with physicians experienced in the management of porphyrias.
For intravenous infusion only.

Dosing recommendation:

- IV infusion of 1-4 mg/kg/day over 30+ minutes for 3-14 days based on clinical signs
- The standard dose in clinical practice is 3 to 4 mg/kg/day
- In more severe cases, the dose may be repeated no earlier than every 12 hours
- No more than 6 mg/kg per 24-hour period

Preparing PANHEMATIN

Step 1 - Calculate Dose of Reconstituted PANHEMATIN for Infusion

When PANHEMATIN is reconstituted with 48 ml Sterile Water for Injection, USP, it contains the equivalent of ~336 mg hematin at a concentration of 7 mg/mL.

$$\text{mL to infuse} = \frac{\text{Prescribed Dosage (mg/kg) x Patient Weight (kg)}}{\text{7 mg/mL Concentration of Reconstituted PANHEMATIN}}$$

Step 2 - Reconstitute PANHEMATIN

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

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 from bottle.

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.

*The vial stopper of PANHEMATIN contains natural rubber latex, which may cause allergic reactions.

IMPORTANT SAFETY INFORMATION (Continued)

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Risk of Phlebitis: Phlebitis is possible. Utilize a large arm vein or a central venous catheter for administration to minimize the risk of phlebitis.

Iron and Serum Ferritin: Elevated iron and serum ferritin may occur. Monitor iron and serum ferritin in patients receiving multiple administrations of PANHEMATIN.

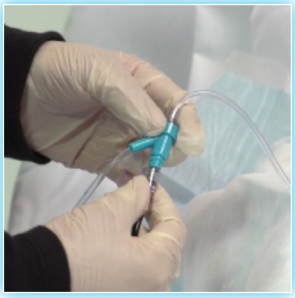
For more information, please see Important Safety Information on page 5 and accompanying full Prescribing Information.

Administering PANHEMATIN® (hemin for injection)

Refer to page 5 for a list of supplies needed to infuse PANHEMATIN.

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.

IMPORTANT SAFETY INFORMATION (Continued)

Anticoagulant Effects: PANHEMATIN has transient and mild anticoagulant effect. Avoid concurrent anticoagulant therapy.

Renal Effects: Reversible renal shutdown has been observed with an excessive hematin dose (12.2 mg/kg in a single infusion). Strictly follow recommended dosage guidelines.

Transmissible Infectious Agents: PANHEMATIN may carry a risk of transmitting infectious agents, e.g., viruses, and theoretically, the Creutzfeldt-Jakob disease (CJD) agent. There is also the possibility that unknown infectious agents may be present in the product.

For more information, please see Important Safety Information on page 5 and accompanying full Prescribing Information.

Step 2 - Infuse PANHEMATIN® (hemin for injection)

Verify the dose of PANHEMATIN the patient will be receiving. Use an infusion pump to ensure accuracy of dosing and administration time.

Infuse the reconstituted PANHEMATIN immediately. PANHEMATIN contains no preservative and undergoes rapid chemical decomposition in solution.

1. Attach the 0.45-micron filter to the IV 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 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.

IMPORTANT SAFETY INFORMATION (Continued)

The most common adverse reactions (>1% of patients) are headache, pyrexia, infusion site reactions, and phlebitis.

To report SUSPECTED ADVERSE REACTIONS, contact Recordati Rare Diseases Inc. at 1-888-575-8344, or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Drug Interactions: Avoid CYP inducing drugs such as estrogens, barbituric acid derivatives and steroid metabolites which induce δ-aminolevulinic acid synthetase 1 (ALAS1) through a feedback mechanism.

For more information, please see Important Safety Information on page 5 and accompanying full Prescribing Information.

Supply List

Reconstitution

1 Vial of PANHEMATIN® (hemin for injection)
1 Bottle Sterile Water for Injection, USP
1 60 mL syringe with 18-20 gauge needle
2 Alcohol wipes
1 Protective gloves

Infusion

1 Vial of reconstituted PANHEMATIN
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 0.45-micron or smaller filter
1 IV tubing with vented spike, or vented spike adapter
1 Huber needle and injection cap
1 Central line dressing kit
1 Saline flush syringe
2 Alcohol wipes
1 Protective gloves
1 IV bag label

PANHEMATIN® (hemin for injection)

INDICATIONS AND USAGE

PANHEMATIN is a hemin for injection 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 PANHEMATIN, consider an appropriate period of carbohydrate loading (i.e., 400 g glucose/day for 1 to 2 days).
- 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. PANHEMATIN is not effective in repairing neuronal damage.

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Drug Interactions: Avoid CYP inducing drugs such as estrogens, barbituric acid derivatives and steroid metabolites which induce δ-aminolevulinic acid synthetase 1 (ALAS1) through a feedback mechanism.

PANHEMATIN® (hemin for injection), for intravenous infusion only, is available as powder for reconstitution in 350 mg vials.

Please see accompanying full Prescribing Information.

How to Order PANHEMATIN® (hemin for injection)

Order from your primary wholesaler or Cencora (formerly ASD Healthcare)

Cencora:
- Phone: 1-800-746-6273
- FAX: 1-800-547-9413
- Email: service@asdhealthcare.com

Hours of Operation:
- Monday-Thursday 7 AM – 6:30 PM CT
- Friday 7 AM – 6:30 PM CT

Weekend delivery <u>available on request</u> with an additional shipping cost

Orders placed by	Delivered
Monday-Thursday 6:30 PM CT	Priority Overnight for 10:30 AM delivery*
Friday 6:00 PM CT	Priority Overnight delivery for 10:30 AM next business day
Saturday Delivery	Must be requested when order is placed and subject to additional shipping cost

Include any specific delivery instructions when ordering. New to ordering PANHEMATIN? Ask for expedited account setup.

***10:30 AM delivery available in most areas**

PANHEMATIN is supplied as a sterile, lyophilized black powder in single dose dispensing vials (NDC 55292-702-54) in a carton (NDC 55292-702-55). The vial stopper contains natural rubber latex. Store lyophilized powder at 20-25°C (68-77°F).

Additional Phone Numbers

For assistance with insurance questions, patient assistance program, or copay assistance program, call: 1-866-209-7604.

For medical questions, call Recordati Rare Diseases Medical Information: 1-888-575-8344

To view a demonstration video of the information in this brochure, go to: www.Panhematin.com.

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