

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION

Panhematin®
hemin for injection

Read this carefully before you start taking **PANHEMATIN** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **PANHEMATIN**.

What is PANHEMATIN used for?

PANHEMATIN is a hemin for injection prescription medication used to relieve repeated attacks of acute intermittent porphyria (AIP) related to the menstrual cycle in affected women, after initial carbohydrate therapy is known or suspected to be inadequate. PANHEMATIN should not be used for preventing attacks of porphyria.

If you have an AIP attack, your doctor will determine the best course of treatment. After 1-2 days of glucose therapy, your doctor may recommend you start PANHEMATIN. PANHEMATIN should only be used by doctors experienced in the management of porphyrias in hospitals where the recommended clinical and laboratory diagnostic and monitoring practices are available.

How does PANHEMATIN work?

The goal of treatment with PANHEMATIN is to reduce the production and build-up of certain chemicals in your body. This chemical build-up is what causes symptoms such as severe abdominal pain

What are the ingredients in PANHEMATIN?

Medicinal ingredients: hemin

Non-medicinal ingredients: sodium carbonate and sorbitol. The diluent contains sterile water for injection.

PANHEMATIN comes in the following dosage forms:

Powder for reconstitution for injection 268 mg/vial

Do not use PANHEMATIN if:

- you are allergic to this drug

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take PANHEMATIN. Talk about any health conditions or problems you may have, including if you:

- you are pregnant or planning to become pregnant
- you are breastfeeding, unless clearly needed

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with PANHEMATIN:

- When taking PANHEMATIN, do not take drugs such as estrogens (e.g., oral contraceptives), barbiturates (drugs that help with sleep and used to treat epilepsy) or steroids (body hormone-like drugs), because such drugs can trigger an attack or make an attack worse.

How to take PANHEMATIN:

PANHEMATIN is given through an IV needle into a large arm vein or a central line. Small arm veins should not be used since vein inflammation has been reported.

Usual dose:

- 0.8 to 3.1 mg/kg/day for 3 to 14 days based on the clinical signs. The standard dose in clinical practice is 2.3 to 3.1 mg/kg/day.
- Repeat dose in more severe cases no earlier than every 12 hours. Do not exceed 4.6 mg/kg in any 24 hour period.

Overdose:

If you think you have taken too much Panhematin[®], contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

What are possible side effects from using PANHEMATIN?

These are not all the possible side effects you may feel when taking PANHEMATIN. If you experience any side effects not listed here, contact your healthcare professional.

Most common side effects are headache, fever, infusion site reactions, and vein inflammation.

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store PANHEMATIN at room temperature (20-25°C)

Keep out of reach and sight of children.

If you want more information about PANHEMATIN:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website; the manufacturer's website <http://www.recordatirarediseases.ca/>, or by calling Recordati Rare Diseases Canada Inc. at 905-827-1300.

This leaflet was prepared by Recordati Rare Diseases Canada Inc.

Last Revised July 13, 2018