

A guide for patients taking PrMONOFERRIC®

MONOFERRIC is used to treat adults with iron deficiency anemia. This condition happens when the body doesn't have enough iron. MONOFERRIC is given when you cannot tolerate iron given by mouth (oral) or when oral iron therapies do not work for you.

Pr Monoferric®
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Visit **www.MONOFERRIC.ca** to find other helpful MONOFERRIC resources, such as an infusion clinic locator and printable patient booklet in **6 languages**:

- English
- French
- Spanish
- Chinese (Simplified)
- Chinese (Traditional)
- Punjabi

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Use this booklet to help you understand more about your MONOFERRIC treatment, and how to identify and manage possible side effects.

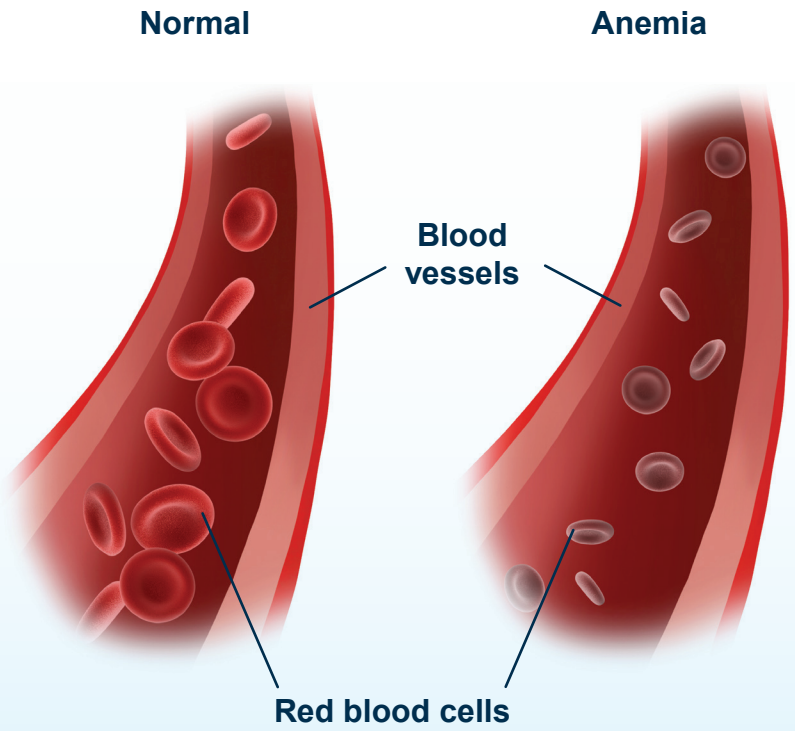
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What is iron deficiency anemia (IDA)?

IDA is a condition caused by low levels of iron in the body.

Iron plays a key role in various functions of the body, including the production of hemoglobin, the molecule in your red blood cells that carries oxygen throughout your body.

If there is not enough iron, then your body will make fewer and smaller red blood cells and have less hemoglobin, resulting in insufficient oxygen delivery to tissues.



What are the causes of IDA?

There are many causes of IDA, including:

- Blood loss including:
  a. Heavy menstrual periods or bleeding during childbirth
  b. Surgery
- Not getting enough iron in food, which can happen in people who need a lot of iron, such as:
  a. Pregnant women
  b. Small children
  c. Teens
- Problems absorbing iron
- Multiple mechanisms associated with inflammation
- Increased iron requirements

MONOFERRIC is used in patients who cannot tolerate oral iron (taken by mouth) or for whom oral iron therapies do not work.

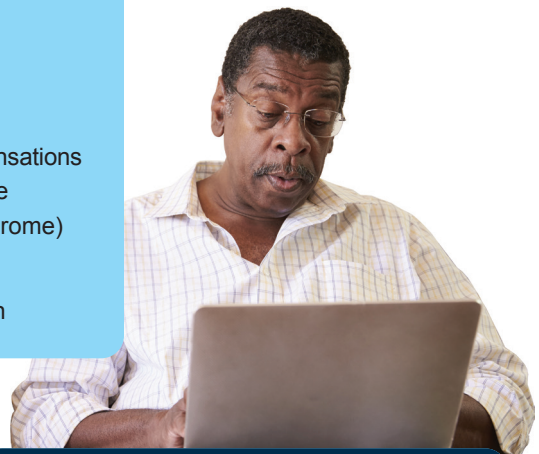


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Signs and symptoms of IDA

Signs of IDA may include:

- Pale or yellow skin
- Brittle nails
- Hair loss
- Unpleasant or uncomfortable sensations in the leg and an irresistible urge to move them (restless leg syndrome)
- Sore or smooth tongue
- Cracks at the sides of the mouth





Symptoms of IDA may include:

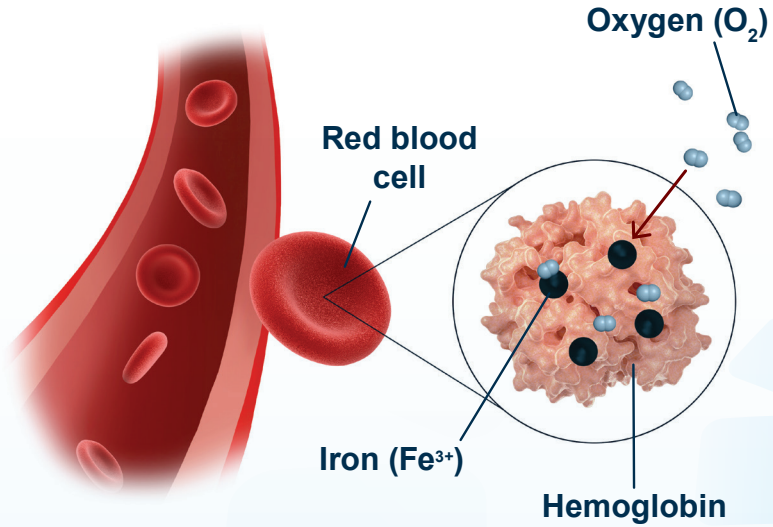
- Unexplained fatigue or lack of energy
- Shortness of breath or chest pain, especially with activity
- Unexplained generalized weakness
- Rapid heartbeat
- Pounding or “whooshing” in the ears
- Headache, especially with activity
- Feeling cold in the hands and feet
- Difficulty concentrating
- Dizziness
- Unusual cravings for non-food items such as ice or clay (medical term: pica)

Please keep in mind that you may not notice any signs and symptoms of IDA. Your doctor did a blood test to determine your iron need before prescribing MONOFERRIC, and will do other tests such as measuring your weight to determine how much MONOFERRIC you will be given.

What is MONOFERRIC and how does it work?

MONOFERRIC is a dark brown, non-transparent, sterile solution containing iron-bound molecules that is used to raise the iron levels of adult patients who cannot tolerate or who do not respond to oral iron therapies.

MONOFERRIC is used to deliver iron to your body and replenish your body’s iron stores. After MONOFERRIC is given, it is taken up by cells particularly in the liver and spleen, from where the iron is slowly released. Iron is needed to make hemoglobin, and hemoglobin is necessary for red blood cells to be able to carry oxygen throughout your body.



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What conditions should my doctor know about before I use MONOFERRIC?

Before you use MONOFERRIC, talk to your doctor if you:

- Have a history of drug allergies
- Have lupus (an immune system disease where the body's own defence system attacks normal tissue)
- Have rheumatoid arthritis (joint swelling)
- Have severe asthma, eczema (itchy, red skin), or other allergies
- Have low blood pressure (hypotension)
- Have a severe infection
- Are older than 65 years of age
- Are taking other medicines, including any drugs, vitamins, minerals, natural supplements, or alternative medicines (MONOFERRIC can reduce the effect of oral iron)



Talking to your doctor about any health conditions or problems you may have, including those listed above, will help avoid side effects and ensure the proper use of MONOFERRIC.



Do NOT use MONOFERRIC if:

- You are allergic to ferric derisomaltose or any of the ingredients in this medicine or components of the container
- You have a history of serious allergies to other injectable iron medications
- You have anemia **not** caused by iron deficiency (hemolytic anemia)
- You have too much iron (iron overload) or a problem in the way your body uses iron (hemochromatosis, hemosiderosis)
- You have liver problems (cirrhosis, hepatitis)

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What should I expect **during** my MONOFERRIC treatment?

Everyone's usual dose of MONOFERRIC is different. Your healthcare professional will determine the exact dose depending on your weight, your blood hemoglobin levels, the amount of iron you need, and your concurrent conditions.

It may be given only once or once per week until your condition is treated. MONOFERRIC will be given to you either:

- through a vein in your arm. This is called an intravenous (IV) infusion or IV injection
  – An IV infusion will be done over a minimum of 20–30 minutes
  – An IV injection will be done over about 2 minutes
- directly into the dialyzer during a hemodialysis session

About 4 weeks after your MONOFERRIC treatment is complete, your healthcare professional will assess you to check whether you need more treatment.

During your treatment, you will be carefully observed by a doctor or nurse for possible side effects.

Injectable iron products can cause serious allergic reactions, including fatal anaphylaxis or anaphylactoid reactions. MONOFERRIC can cause serious cases of hypotension (low blood pressure).

MONOFERRIC will be given in a location where any allergic events can be treated immediately. You will be carefully observed for signs and symptoms of an allergic reaction, including monitoring of blood pressure and pulse, during and for at least 30 minutes after each MONOFERRIC treatment.

Get immediate medical help and make sure that your doctor or nurse stops your MONOFERRIC treatment if you experience any of the following symptoms of an allergic reaction while receiving MONOFERRIC:

- Dizziness or light-headedness
- Swelling of your face, tongue, or throat
- Difficulty swallowing
- Itching, rash, or hives
- Difficulty breathing
- Nausea or abdominal pain
- Low blood pressure

To ensure that MONOFERRIC is being administered properly, make sure to tell your healthcare professional if you feel any irritation or see brown discolouration of the skin around the injection site, as they will need to stop the administration.

Incorrect administration of MONOFERRIC may cause leakage at the injection site. This may irritate the skin. As well, it is possible that the colour of your skin at the site and on other areas of your body may become brown. This may be long-lasting. Tell your doctor or nurse immediately if you notice any leakage. They will need to stop the administration.



What should I expect **after** my MONOFERRIC treatment?

You will be monitored for at least 30 minutes by healthcare professionals after each MONOFERRIC treatment, and your doctor will schedule blood tests to monitor your hemoglobin levels and iron stores.

After your treatment with MONOFERRIC, give yourself time to see how you feel before driving a vehicle or using machinery.

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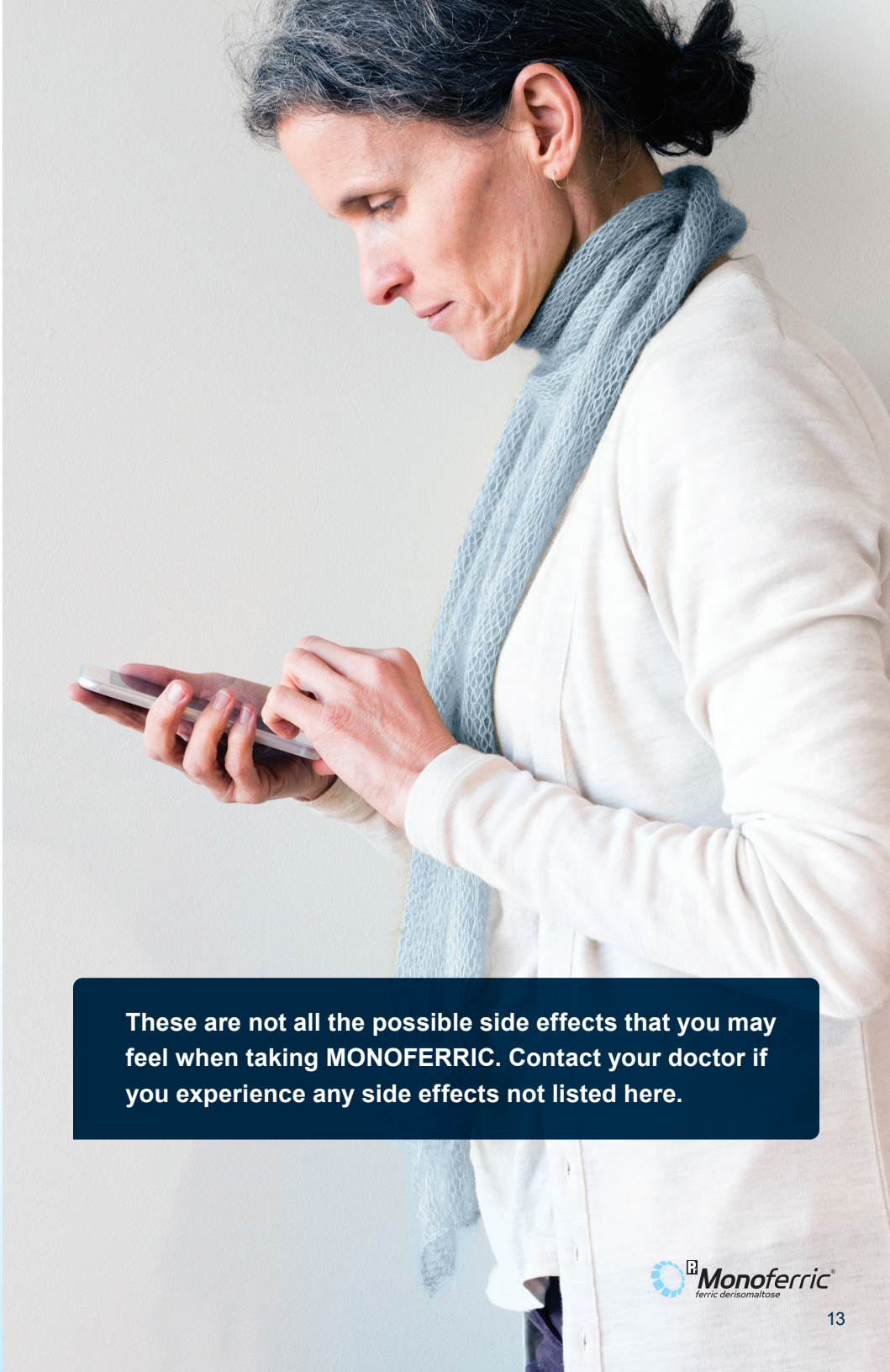
Possible side effects of MONOFERRIC

Side effects of MONOFERRIC may include:

- Abdominal pain
- Back pain
- Chest pain
- Constipation
- Diarrhea
- Discoloured stool
- Dizziness
- Fatigue
- Fever
- Flu-like illness may occur a few hours to several days after injection and is typically characterised by symptoms such as high temperature, and aches and pains in the muscles and joints
- Flushing
- Headache
- Indigestion
- Joint pain
- Muscle pain or spasms
- Nausea
- Vomiting
- Skin exfoliation or discolouration
- Itchy skin
- Sore throat
- Cough
- Inflammation of nose and throat
- Swelling of hands and feet
- Taste disturbance
- Tingling sensation

Other warnings you should know about

- **Hypophosphatemia:** May cause low levels of phosphate in the blood
- **Driving and using machinery:** Give yourself time after taking MONOFERRIC to see how you feel before driving a vehicle or using machinery
- **Female patients:**
  - **Pregnancy:** Inform your doctor if you are pregnant, become pregnant, think you are pregnant, or are planning to become pregnant. There are specific risks you should discuss with your healthcare professional. You can have a serious allergic reaction while receiving MONOFERRIC, which can cause serious harm to your unborn baby. They may develop an unusually slow heart rate. This usually lasts for a short time. If you are receiving this medicine while pregnant, your healthcare professional should carefully monitor your unborn baby.
  - **Breast feeding:** MONOFERRIC passes into breast milk. If you are breastfeeding or are planning to breastfeed, talk to your healthcare professional.



These are not all the possible side effects that you may feel when taking MONOFERRIC. Contact your doctor if you experience any side effects not listed here.

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What serious side effects should I report to my healthcare professional?

Talk to your doctor if you experience any of the following uncommon serious side effects:

Condition	Symptoms
Pneumonia	Lung infection causing chest pain, coughing, fever, and fatigue
Urinary tract infection	Burning sensation when urinating, cloudy or bloody urine, strong odour
High blood pressure (hypertension)	Headaches, dizziness, blurred vision, chest pain or shortness of breath
Low blood pressure (hypotension)	Fainting, dizziness or light-headedness with standing
Decrease in number of red blood cells (anemia)	Dizziness, feeling tired and weak, loss of energy, shortness of breath

Where can I go to learn more about MONOFERRIC?

For more information about MONOFERRIC:

- Talk to your healthcare professional
- Consult the “Patient Medication Information” leaflet included in the product package for complete information regarding precautions and adverse events

Also talk to your doctor if you have a troublesome symptom/side effect that is not listed here or becomes bad enough to interfere with your daily activities, or if you experience any of the following rare side effects:

- Congestive heart failure (heart does not pump blood as well as it should): shortness of breath, fatigue and weakness, swelling in ankles, legs and feet, cough, fluid retention, lack of appetite, nausea, rapid or irregular heartbeat, reduced ability to exercise
- Dyspnea (shortness of breath, difficulty breathing)
- Myocardial infarction (heart attack): pressure or squeezing pain between the shoulder blades, in the chest, jaw, left arm or upper abdomen, shortness of breath, dizziness, fatigue, light-headedness, clammy skin, sweating, indigestion, anxiety, feeling faint and possible irregular heartbeat
- Rash: areas of redness on the skin that are itchy or painful
- Pyrexia (fever)
- Seizures (fits or convulsions)
- Sepsis (serious infection)
- Syncope (fainting): a temporary loss of consciousness due to a sudden drop in blood pressure

Hypersensitivity (allergic) reactions, which are possibly life-threatening, may also occur. The symptoms may include fever, joint pain, nausea, vomiting, chest pain, rash, hives, swelling of the face/lips/tongue/throat, and/or difficulty swallowing/breathing. Stop taking MONOFERRIC and immediately seek medical help if you experience any of these symptoms.

Notes:

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For additional MONOFERRIC information and resources, visit **www.MONOFERRIC.ca**.

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