

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PART III: PATIENT MEDICATION INFORMATION

^{Pr}MONOFERRIC™ Iron Isomaltoside 1000 for Injection

Read this carefully before you start taking **MONOFERRIC** 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 **MONOFERRIC**.

Serious Warnings and Precautions

MONOFERRIC should not be used in patients allergic to this drug or other injectable iron products.

MONOFERRIC should not be used in patients with any known history of multiple allergies.

MONOFERRIC can cause severe side effects, such as:

- Allergic reactions causing death (anaphylaxis)
- Serious cases of low blood pressure (hypotension)

Only use MONOFERRIC if personnel are able to treat severe allergic reactions without delay. You will be monitored for signs and symptoms of an allergic reaction for at least 30 minutes after treatment with MONOFERRIC.

What is MONOFERRIC used for?

MONOFERRIC is used to raise your level of iron (sometimes called ‘iron deficiency anaemia’) when:

- You cannot tolerate oral iron or
- Oral iron therapies do not work for you

How does MONOFERRIC work?

MONOFERRIC is used to replenish your body’s iron stores. Iron is needed to make haemoglobin, which allows red blood cells to carry oxygen throughout your body.

What are the ingredients in MONOFERRIC?

Medicinal ingredient: iron isomaltoside 1000

Non-medicinal ingredients: hydrochloric acid, sodium hydroxide, water for injection

MONOFERRIC comes in the following dosage forms:

100 mg elemental iron/mL

Do not use MONOFERRIC if:

- You are allergic to this drug or any of the ingredients
- You have a history of serious allergies to other injectable iron medications

- You have a history of multiple types of allergies
- You have anemia **not** caused by iron deficiency (hemolytic anaemia)
- 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)

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take MONOFERRIC. Talk about any health conditions or problems you may have, including 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 pregnant or planning to become pregnant
- Are breastfeeding or planning to breastfeed
- Are older than 65 years of age

Other warnings you should know about:

- Incorrect administration of MONOFERRIC may cause leakage of the product at the injection site. This may lead to irritation of the skin and possibly long lasting brown discoloration at the site of injection. Tell your doctor or nurse immediately if you notice any leakage. They will need to stop the administration.
- Do not become pregnant while taking MONOFERRIC as it may harm your unborn child. Use effective methods of birth control while taking MONOFERRIC. If you do become pregnant while taking MONOFERRIC, tell your doctor right away.
- MONOFERRIC may pass into breast milk. Do not breastfeed while you are taking MONOFERRIC. If you are planning to breastfeed, tell your doctor.

Give yourself time after taking MONOFERRIC to see how you feel before driving a vehicle or using machinery.

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 MONOFERRIC:

- MONOFERRIC can reduce the effect of oral iron.

How to take MONOFERRIC:

Your doctor will calculate how much MONOFERRIC you will be given. The dose will be based on your weight and iron need.

Your doctor or nurse will give MONOFERRIC in one of the following ways:

- an injection in your vein of up to 500 mg of iron (over approximately 2 minutes) up to once a week
- an infusion in your vein of up to 1500 mg of iron (over approximately 20-30 minutes), once a week
- directly into the dialyzer during a hemodialysis session

MONOFERRIC will be given in a location where any allergic events can be treated immediately.

You will be carefully observed during MONOFERRIC treatment and for at least 30 minutes after by your doctor or nurse. If you have any of the following symptoms of an allergic reaction or begin to feel unwell while receiving MONOFERRIC, tell your doctor or nurse right away:

- Dizzy or light-headed
- Swelling of your face, tongue or throat
- Difficulty swallowing
- Itching, rash or hives
- Difficulty breathing
- Nausea or abdominal pain

Overdose:

If you think you have taken too much MONOFERRIC, 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 MONOFERRIC?

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

Side effects of MONOFERRIC may include the following:

- abdominal pain
- back pain
- constipation
- cough
- difficulty breathing (dyspnoea)
- dizziness
- fatigue
- headache
- indigestion (dyspepsia)
- joint pain
- muscle pain
- muscle spasms
- muscle weakness
- nausea
- rash

- skin exfoliation
- itchy skin (pruritus)
- skin discolouration
- sore throat
- inflammation of nose and throat (nasopharyngitis)
- pneumonia
- swelling of hands and feet (peripheral edema)
- taste disturbance (dysgeusia)
- tingling sensation (paraesthesia)
- urinary tract infection

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
UNCOMMON			
Allergic Reaction (hypersensitivity reaction): possibly life threatening dizziness, severe itching, hives, nausea, difficulty breathing, rash, low blood pressure		√	√
Malignant neoplasm progression (an existing tumor gets worse)		√	
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		√	
Diarrhea: loose or watery and frequent stools		√	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
RARE			
Pyrexia: fever		√	
Seizures (fits or convulsions)		√	
Sepsis (serious infection)		√	
Vomiting		√	

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.

<p>Reporting Side Effects</p> <p>You can report any suspected side effects associated with the use of health products to Health Canada by:</p> <ul style="list-style-type: none"> • Visiting the Web page on Adverse Reaction Reporting (http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php) for information on how to report online, by mail or by fax; or • Calling toll-free at 1-866-234-2345. <p><i>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.</i></p>
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Storage:

Keep out of reach and sight of children.

Store between 15-30 °C. Do Not Freeze.

If you want more information about MONOFERRIC:

- 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 www.pfizer.ca, or by calling 1-800-463-6001.

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