

## PATIENT MEDICATION INFORMATION

### READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **MONOFERRIC**<sup>®</sup>

#### **Ferric Derisomaltose (also known as 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**

Do not use MONOFERRIC if you:

- are allergic to this drug, or
- are allergic to other injectable iron products.

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

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 during and after your treatment with MONOFERRIC.

#### **What is MONOFERRIC used for?**

MONOFERRIC is used to treat adults with iron deficiency anaemia. This condition happens when the body doesn't have enough iron. MONOFERRIC is given when:

- you cannot tolerate iron that is taken by mouth (oral), 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: ferric derisomaltose (also known as iron isomaltoside 1000)

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

#### **MONOFERRIC comes in the following dosage forms:**

Solution: 100 mg / mL elemental iron (as ferric derisomaltose)

#### **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 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 older than 65 years of age

**Other warnings you should know about:**

- Injectable iron products can cause serious side effects including:
  - **Hypersensitivity reactions** which happen when the immune system overreacts and causes harm to the body. Such reactions have been seen even after treatments that were administered without issue.
  - **Infections**

See the 'Serious side effects and what to do about them' table, below, for more information on these and other serious side effects.

- Taking MONOFERRIC may cause **low levels of phosphate in the blood (hypophosphatemia)**. This hypophosphatemia may not be permanent. You may not know you have hypophosphatemia as you may not have any symptoms or complications.
- 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.
- Before and during your treatment with MONOFERRIC, you will have blood tests done to check the level of iron in your blood. Your healthcare professional will also measure your blood pressure and heart rate before, during and 30 minutes after each MONOFERRIC administration.
- Give yourself time after taking MONOFERRIC to see how you feel before driving a vehicle or using machinery.

- **Female patients:**

Pregnancy:

- Do not become pregnant while taking MONOFERRIC. It may harm your unborn child.
- Use effective methods of birth control while taking MONOFERRIC.
- Tell your healthcare professional right away if you are pregnant, become pregnant, think you are pregnant or are planning on becoming pregnant. 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.

Breastfeeding:

- MONOFERRIC passes into breast milk. If you are breastfeeding or are planning to breastfeed, talk to your healthcare professional.

**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 or nurse will give MONOFERRIC to you. 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; or
- directly into the dialyzer during a hemodialysis session.

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

A doctor or nurse will monitor you carefully during your MONOFERRIC treatment and for at least 30 minutes afterwards. 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

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

**Usual dose:** The usual dose of MONOFERRIC is different for everyone. Your doctor will calculate how much MONOFERRIC to give you. Your exact dose will depend on your weight, your blood hemoglobin levels and the amount of iron you need. Patients who weigh more than 50 kg, may receive a fixed amount of 1000 mg MONOFERRIC.

**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.

- 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
- muscle spasms
- nausea
- vomiting
- skin exfoliation
- itchy skin
- skin discolouration
- sore throat
- cough
- inflammation of nose and throat
- swelling of hands and feet
- taste disturbance
- tingling sensation

MONOFERRIC can cause abnormal blood test results including low levels of phosphate. Your doctor will decide when to do blood tests and will interpret the results.

<b>Serious side effects and what to do about them</b>			
<b>Symptom / effect</b>	<b>Talk to your healthcare professional</b>		<b>Stop taking drug and get immediate medical help</b>
	<b>Only if severe</b>	<b>In all cases</b>	
<b>UNCOMMON</b>			
<b>Pneumonia:</b> lung infection causing chest pain, coughing, fever and fatigue		√	
<b>Urinary tract infection:</b> burning sensation when urinating, cloudy or bloody urine, strong odour		√	
<b>High blood pressure</b> (hypertension): headaches, dizziness, blurred vision, chest pain or shortness of breath		√	
<b>Low blood pressure</b> (hypotension): fainting, dizziness or light-headedness with standing		√	
<b>Decrease in number of red blood cells</b> (anemia): dizziness, feeling tired and weak, loss of energy, shortness of breath		√	
<b>RARE</b>			
<b>Congestive Heart Failure</b> (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		√	
<b>Dyspnea</b> (shortness of breath, difficulty breathing)		√	
<b>Myocardial infarction</b> (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		√	√
<b>Rash:</b> areas of redness on the skin that are itchy or painful		√	
<b>Pyrexia:</b> fever		√	
<b>Seizures</b> (fits or convulsions)		√	
<b>Sepsis</b> (serious 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	
<b>Syncope</b> (fainting): a temporary loss of consciousness due to a sudden drop in blood pressure		√	
<b>UNKNOWN</b>			
<b>Hypersensitivity reactions</b> (allergic reactions) – which are possibly life-threatening: fever, joint pain, nausea, vomiting, chest pain, rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing			√

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

<p><b>Reporting Side Effects</b></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"> <li>• Visiting the Web page on Adverse Reaction Reporting (<a href="https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html">https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html</a>) for information on how to report online, by mail or by fax; or</li> <li>• Calling toll-free at 1-866-234-2345.</li> </ul> <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](http://www.pfizer.ca), or by calling 1-800-463-6001.

This leaflet was prepared by Pharmacosmos A/S.

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