

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

FERRLECIT®

Sodium Ferric Gluconate Complex in Sucrose Injection

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

Serious Warnings and Precautions

- Injectable iron products including **FERRLECIT** can cause serious allergic reactions, including fatal anaphylaxis or anaphylactoid reactions.
- Only use **FERRLECIT** 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 **FERRLECIT**.
- **FERRLECIT** should only be used in clinical or hospital setting.

What is **FERRLECIT used for?**

FERRLECIT is used for the treatment of iron deficiency anemia. This condition occurs when your body does not have enough iron. It is used in adult patients with chronic kidney disease undergoing hemodialysis who are receiving supplemental erythropoietin therapy.

How does **FERRLECIT work?**

FERRLECIT is used to replenish your body's iron levels that is lost during hemodialysis. Iron is needed to make hemoglobin, which allows red blood cells to carry oxygen throughout your body.

What are the ingredients in **FERRLECIT?**

Medicinal ingredients: Sodium ferric gluconate complex

Non-medicinal ingredients: Benzyl alcohol, sodium carbonate anhydrous, sodium carbonate decahydrate, water for injection

****FERRLECIT** comes in the following dosage forms:**

Solution: 12.5 mg/mL elemental iron

Do not use **FERRLECIT if:**

- you have low red blood cell count (anemias) not associated with iron deficiency.
- you have too much iron (iron overload).

- you have a problem in the way your body uses iron (iron utilization disorders).
- you are allergic to sodium ferric gluconate complex or any other ingredients in FERRLECIT. If you are not sure about this, talk to your healthcare professional before taking FERRLECIT.
- you have history of serious allergies to other injectable iron products.
- you have severe liver problems.
- you have severe kidneys problems.

FERRLECIT must NOT be used in newborn infants as it contains benzyl alcohol.

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

- have genetic diseases affecting red blood cells or other anemias that do not respond to iron treatment (refractory).
- have known allergies.
- have a history of severe asthma, eczema or other atopic allergy.
- have immune or inflammatory conditions (e.g. rheumatoid arthritis, systemic lupus erythematosus, Crohn's disease).

Other warnings you should know about:

Monitoring and tests: Your doctor will do blood tests to monitor your iron levels before and during your treatment with FERRLECIT.

Female patients:

- If you are pregnant or plan to become pregnant, there are specific risks you should discuss with your healthcare professional.
- FERRLECIT may cause serious allergic reactions. When this happens, your unborn baby may develop an unusually low heart rate (a condition known as fetal bradycardia). This can cause serious harm to your unborn baby.
- If you become pregnant while you are taking FERRLECIT, tell your healthcare professional right away.
- It is not known if FERRLECIT passes through your breast milk. Tell your healthcare professional if you are breastfeeding or plan to breastfeed.

Children (under 18 years of age): FERRLECIT is NOT for use in children.

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 FERRLECIT:

- Oral iron preparations
- Angiotensin converting enzyme (ACE) inhibitors, medicine that lower your blood pressure

How to take FERRLECIT:

FERRLECIT will be given to you by your healthcare professional. It may be given to you by either:

- Infusion into your vein (intravenous infusion) over 1 hour; or
- Slow injection into your vein (intravenous injection)

You will be given FERRLECIT in a location where any allergic events can be treated immediately. Your healthcare professional will carefully monitor you during treatment, and for at least 30 minutes afterwards.

Usual dose:

10 mL

Your healthcare professional will give you the lowest dose needed to maintain iron levels. You may need more than one treatment.

Overdose:

If you think you, or a person you are caring for, have been given too much FERRLECIT, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

What are possible side effects from using FERRLECIT?

These are not all the possible side effects you may have when taking FERRLECIT. If you experience any side effects not listed here, tell your healthcare professional.

- Injection site reaction
- Fatigue, drowsiness
- Headache, dizziness
- Abdominal pain
- Infection
- Cramps
- Fever, chills, flu-like symptoms
- Upper respiratory infection, such a cold
- Tingling sensation
- Nausea, vomiting and/or diarrhea
- Back pain
- Muscle pain
- Arm pain
- Joint stiffness
- Rash, itchy skin
- Increased sweating
- Swollen lymph nodes
- Altered sense of taste

FERRLECIT can cause abnormal blood test results, including high or low level of potassium and low level of sugar. Your healthcare professional will decide when to perform blood tests and will interpret the

results

Serious side effects and what to do about them			
Symptoms	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON			
Chest pain: tightness or pain in the chest		✓	
Dyspnea (shortness of breath): difficulty breathing		✓	
Hypertension (high blood pressure): shortness of breath, fatigue, dizziness or fainting, chest pain or pressure, swelling in your ankles and legs, bluish colour to your lips and skin, racing pulse or heart palpitations		✓	
Hypotension (low blood pressure): dizziness, fainting, light-headedness, blurred vision, nausea, vomiting, fatigue (may occur when you go from lying or sitting to standing up)		✓	
Tachycardia (abnormally fast heartbeat): dizziness, light headedness, shortness of breath, racing heart		✓	
UNKNOWN			
Anemia (decreased number of red blood cells): fatigue, loss of energy, looking pale, shortness of breath, weakness		✓	
Angina pectoris (not enough oxygen to the heart muscle): discomfort in the shoulder, arm, back, throat, jaw or teeth; pain or pressure in the chest		✓	
Bradycardia (abnormally slow heartbeat): chest pain, confusion, dizziness, light-headedness, easy tiring during physical exercise, fatigue, fainting, shortness of breath		✓	
Circulatory collapse: rapid breathing, chest pain, fainting		✓	
Conjunctivitis (eye infection): itchy, red eyes with discharge, and swelling		✓	
Hemolysis (breakdown of red blood cells): pale skin, fever, dizziness,		✓	

Serious side effects and what to do about them			
Symptoms	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
confusion, inability for physical activity			
Hypersensitivity reactions (allergic reactions) – which is sometimes life-threatening: fever, joint pain, nausea, vomiting, chest pain, rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing			✓
Kounis syndrome: a mixture of symptoms and signs of an allergic reaction and heart attack or unstable angina, with chest pain, shortness of breath, faintness, nausea, vomiting, syncope, pruritus, urticaria, sudden, heavy sweating, unusual paleness, palpitations, hypotension, slow heartbeat		✓	
Leukocytosis (increased number of white blood cells)		✓	
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		✓	
Peripheral edema (swelling of the legs or hands caused by fluid retention): swollen or puffy legs or hands, feeling heavy, achy or stiff		✓	
Pulmonary edema (excess fluid in the lungs): difficulty breathing that worsens with activity or when lying down, extreme shortness of breath, wheezing or gasping for breath, cold clammy skin, irregular heartbeat, cough that produces frothy sputum, blue-tinged lips		✓	
Seizures (convulsions): spasms, shaking or fits			✓
Urinary tract infection (infection in urinary system including kidneys, ureters, bladder and urethra): Pain or		✓	

Serious side effects and what to do about them			
Symptoms	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
burning sensation while urinating, frequent urination, blood in urine, pain in the pelvis, strong smelling urine, cloudy urine			

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.

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.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:

FERRLECIT will be stored and managed by your healthcare professionals. The instructions below on how to store FERRLECIT is meant for your healthcare professional.

Store at controlled room temperature between 20°C to 25°C (excursions permitted between 15°C to 30°C). Protect from light. Do not freeze.

Parenteral drug products should be inspected visually for particulate matter and discoloration before administration, whenever the solution and container permit. Use immediately after dilution in saline. Discard any unused portion.

Keep out of reach and sight of children.

If you want more information about FERRLECIT:

- 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: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website (www.sanofi.ca), or by calling 1-800-265-7927.

This leaflet was prepared by sanofi-aventis Canada Inc.

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