PACKAGE LEAFLET: INFORMATION FOR THE USER

Ferrologic 20 mg/ml solution for injection/concentrate for solution for infusion

Active substance: Iron

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet

What is in this leaflet:

1. What Ferrologic is and what it is used for

Ferrologic belongs to a group of medicines called iron preparations. It is given directly into a vein.

Ferrologic is used to restore the iron stores in the body in patients who have iron deficiency
The product is intended for use only in the following circumstances:
- in patients who cannot tolerate oral iron therapy (i.e. when taken by mouth);
- in patients who do not take oral iron therapy as recommended;
- in patients where it is necessary to deliver iron rapidly to the iron stores;
- in patients who have medical conditions which mean they cannot properly absorb oral iron, e.g. inflammatory bowel diseases.

Before starting treatment with Ferrologic a blood test should be carried out to ensure treatment with this medicine is appropriate.

2. What you need to know before you use Ferrologic

Do not use Ferrologic
- if you already had an **allergic** (hypersensitive) reaction to **iron preparations** given by injection or infusion in the past or to any of the other ingredients of Ferrologic;
- if you have a history of :
  - **asthma,** narrowing of the airways accompanied by shortness of breath,
  - **rash** or **other allergic skin reactions** with inflammation accompanied by itching and dryness.

  In these cases you are more susceptible to allergic reactions.
- if your **anaemia,** i.e. low amount of red blood cells, is not due to a shortage of iron;
- if you have **too much iron** stored in your body or your body is **unable to use iron properly**;
- in **early pregnancy** (first three months).

Warnings and precautions
Talk to your doctor before you use Ferrologic.

- if you experience severe allergic reactions (anaphylactoid reaction) following intravenous administration of iron preparations that may result in cardiovascular collapse (circulatory collapse with inadequate blood supply to body tissues). Since these reactions may be fatal the medicine should only be given if adequate medical care is available. If a severe allergic reaction occurs Ferrologic must be stopped immediately. If necessary, your doctor will initiate a suitable treatment.
- if you suffer from liver disease. Your doctor will carefully monitor your blood iron levels in case Ferrologic is given.
- if you suffer from acute or chronic infection.
- if you experience allergic reactions, which sometimes involve pain in the joints. These reactions were observed more frequently following an overdose. If the injection is administered too quickly transient low blood pressure may occur.
- It is important that this medicine is given directly into a vein. If it 'leaks' out into the tissues around the vein it can cause a severe reaction with pain, discolouration and swelling around the site where it is being given. Tell your doctor or nurse immediately if you experience any of these symptoms.

Other medicines and Ferrologic
Tell your doctor or pharmacist if you are using, have recently taken or used or might take or use any other medicines, especially **any other iron preparations**.

Ferrologic should not be given at the same time as oral iron preparations, as the absorption of oral iron is reduced. Therefore, if you are switched to iron treatment by mouth it should be started at least five days after the last injection of Ferrologic.

Pregnancy, breast-feeding and fertility
Ferrologic must not be used during the first three months of pregnancy and must be used with caution from the fourth to the ninth month of pregnancy. Ferrologic should only be used if iron preparations given by mouth are ineffective or not tolerated and your iron deficiency is severe. Ferrologic is unlikely to pass into the breast milk and therefore no effects on the breast-fed infant are expected. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines
Some patients may occasionally feel dizzy, drowsy or confused. If this happens, you should not drive or use machinery.

Important information about some of the ingredients of Ferrologic
This medicinal product contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially 'sodium-free'.

3. How to use Ferrologic

Ferrologic should **only** be administered **directly into a vein**, either by slow injection or by infusion. The latter is the preferred route. **Ferrologic must not be injected into a muscle or under the skin**. Before giving the first dose, your doctor should give a small **"test dose"** to check you are not allergic to this product.

The dose of Ferrologic you need, will be calculated from your blood test (concentration of haemoglobin) and your weight. Your doctor will also decide how often, and for how long, you will need this treatment.

Use in children

Ferrologic is NOT recommended for use in children.

If you use more Ferrologic than you should
If you receive more Ferrologic than you need this can lead to an accumulation of excess iron in the body tissues. If this should happen, your doctor will give you appropriate treatment (with a chelating agent) which will remove the excess iron.
If you have any further questions on the use of this product, please ask your doctor.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The assessment of the side effects is based on the following frequencies:

Very common:	more than 1 of 10 patients treated
Common:	less than 1 of 10 and more than 1 of 100 patients treated
Uncommon:	less than 1 of 100 and more than 1 of 1,000 patients treated
Rare:	less than 1 of 1,000 and more than 1 of 10,000 patients treated
Very rare:	less than 1 of 10,000 patients treated
Not known:	frequency can not be estimated from the available data

The following side effects have been reported following the administration of Ferrologic:

Common:
- temporary changes in taste such as metallic taste

Uncommon:
- headache
- dizziness
- low blood pressure
- collapse
- increased blood pressure
- increased heart rate
- palpitations (a noticeably rapid, strong or irregular heartbeat)
- narrowing of the airways accompanied by shortness of breath
- nausea
- vomiting
- abdominal (e.g. stomach) pain
- diarrhoea
- itching
- hives
- rash
- redness
- muscle cramps
- muscle pain/ache
- fever
- shivering
- flushing
- chest pain and chest tightness
- swelling and inflammation reactions (sometimes involving veins) or a burning sensation around the site of injection or infusion

Rare:
- tingling
- "pins and needles"(paraesthesia)
  severe allergic (hypersensitivity) reactions (rarely including joint pain). They can involve swelling of the lips or tongue, wheezing, collapse and, very rarely, convulsions (fits or seizures).
  IF YOU EXPERIENCE A SEVERE ALLERIC REACTION OBTAIN MEDICAL ASSISTANCE IMMEDIATELY.
- swelling of hands and feet
- tiredness
- weakness
- general feeling of illness

Moreover, in spontaneous reports the following side effects have been reported:
Not known:
- decreased alertness
- light-headedness
- confusion
- swelling of face and tongue as well as swelling of joints, increased sweating or back pain.

If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet.

5. How to store Ferrologic

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and the label. The expiry date refers to the last day of that month.

Store in the original package in order to protect from light. Do not freeze.

Stability of Ferrologic after ampoules have been opened or following dilution
Use the ampoules immediately after opening. Use the diluted or undiluted solution immediately. Except for 0.9% of saline solution no other dilution solutions or therapeutic agents are to be used or added.

Do not use Ferrologic if you notice any of the following: sediment or a non-uniform solution. The diluted solution must appear as brown and clear.

Any unused portion of the solution is to be discarded.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Ferrologic contains

The active substance is: iron
as a solution of iron sucrose
[iron(III)-hydroxide sucrose complex]

Each millilitre of solution contains 20 mg iron as iron sucrose [iron(III)-hydroxide sucrose complex].
Each 5 ml ampoule contains 100 mg iron as iron sucrose [iron(III)-hydroxide sucrose complex].

The other ingredients are sodium hydroxide and water for injection.

What Ferrologic looks like and contents of the pack

Ferrologic is a sterile, dark brown, non transparent, aqueous solution of iron intended to be used only for intravenous injection or as a concentrate for solution for infusion.
Ferrologic is supplied in glass ampoules each containing 5 ml solution, which is equivalent to 100 mg iron. The product is supplied in cardboard boxes containing 5 ampoules or in multi-packs comprising 10 packs, each containing 5 ampoules.

Marketing Authorisation Holder

Fresenius Medical Care Nephrologica Deutschland GmbH
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Manufacturer
Fresenius Medical Care Deutschland GmbH
61346 Bad Homburg v.d.H.
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The following information is intended for healthcare professionals only:

Administration:
Ferrologic must only be administered by the intravenous route (by a slow intravenous injection or intravenous drip infusion, the latter is the preferred route of administration as this may help to reduce the risk of hypotensive episodes and paravenous leakage).

Before administering the first therapeutical dose of Ferrologic to a new patient, a test dose of between 1 and 2.5 ml of Ferrologic (20 to 50 mg of iron) should be injected slowly over a period of 1 to 2 minutes. If no adverse reactions occur for a period of 15 minutes after administration, the rest of the initial dose may be administered. Facilities for cardio-pulmonary resuscitation must be available when administering Ferrologic because allergic or anaphylactoid reactions and hypotensive episodes may occur. Ferrologic is a strongly alkaline solution (pH 10.5 - 11.1) and must never be administered by the subcutaneous or intramuscular route, nor is it suitable for TDI (total dose infusion) during which the total necessary iron dose equivalent to the iron depletion, is administered on a single occasion.

Intravenous drip infusion:
Ferrologic must be diluted only in 0.9% sodium chloride solution (normal saline). Each 5 ml ampoule (100 mg iron) of Ferrologic should be diluted in 100 ml of 0.9% saline immediately before infusion (i.e. 2 ampoules in 200 ml, etc. to max. 5 ampoules in 500 ml of normal saline). For stability reasons, dilutions of lower Ferrologic concentrations are not permissible. The solution must be administered at the following rate: 100 ml in at least 15 minutes; 200 ml in at least 30 minutes; 300 ml in at least 1.5 hours; 400 ml in at least 2.5 hours; 500 ml in at least 3.5 hours.

Intravenous injection:
Ferrologic may be administered by slow intravenous injection at a rate of 1 ml undiluted solution per minute (i.e. 5 minutes per ampoule) and not exceeding 2 ampoules Ferrologic (200 mg iron) per

injection. After an intravenous injection, extend and elevate the patient's arm and apply pressure to the injection site for at least 5 minutes to reduce the risk of paravenous leakage.

Injection into dialyser:
Ferrologic may be administered during haemodialysis directly into the venous line of the dialyser under the same procedures as those outlined for intravenous administration.

When the total necessary dose exceeds the maximum daily dose, the administration should be split.

Handling recommendations:
Ampoules should be visually inspected for sediment and damage before use. Only those with sediment free and homogenous solution must be used. The diluted solution must appear as brown and clear.

Incompatibilities
Ferrologic must only be mixed with 0.9% of sodium chloride solution. No other intravenous dilution solutions and therapeutic agents should be used or added as there is the potential for precipitation and/or interaction.

Shelf life after first opening the container:
From a microbiological point of view, the product should be used immediately.

Shelf life after dilution with 0.9% sodium chloride solution:
Chemical and physical in-use stability has been demonstrated for 24 hours at 22 ± 2°C. From a microbiological point of view, the diluted product should be used immediately.