PACKAGE LEAFLET: INFORMATION FOR THE USER

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

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

Active substance: Iron

Read all of this leaflet carefully before you are given 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.
- 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 . 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 receive Ferrologic

You must not receive Ferrologic
- if you are **allergic** (hypersensitive) to the product or any of the other ingredients of this medicine (listed in section 6);
- if you have experienced serious **allergic** (hypersensitive) reactions to other injectable **iron preparations;**.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 or nurse before receiving Ferrologic:

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- **if you have a history of medicine allergy.**
- **if you have systemic lupus erythematosus (SLE).**
- **if you have rheumatoid arthritis.**
- **if you have severe asthma, eczema or other allergies.**
- 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.

How Ferrologic is given
Your doctor or nurse will administer Ferrologic by injection into a vein; the Ferrologic will be administered in a structure where immunoallergic events can receive appropriate and prompt treatment.

You will be observed for at least 30 minutes by your doctor or nurse after each administration.

Other medicines and Ferrologic
Tell your doctor 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
Ferrologic has not been tested in pregnant women. It is important to tell your doctor if you are pregnant, think you may be pregnant, or are planning to have a baby.
If you become pregnant during treatment, you must ask your doctor for advice. Your doctor will decide whether or not you should be given this medicine.

Breast-feeding
If you are breast-feeding, ask your doctor for advice before you are given Ferrologic.

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 Ferrologic is administered

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**.

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 receive 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: may affect more than 1 in 10 people
Common: may affect up to 1 in 10 people
Uncommon: may affect up to 1 in 100 people
Rare: may affect up to 1 in 1,000 people
Very rare: may affect up to 1 in 10,000 people
Not known: frequency cannot 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 allergic 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.

Reporting of side effects
If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

(to be completed nationally)

By reporting side effects you can help provide more information on the safety of this medicine.

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. Not all pack sizes may be marketed.

Marketing Authorisation Holder
Fresenius Medical Care Nephrologica Deutschland GmbH
61346 Bad Homburg v.d.H.
Germany

Manufacturer
Fresenius Medical Care Deutschland GmbH
61346 Bad Homburg v.d.H.
Germany

For any information about this medicine, please contact the local representative/distributor of the Marketing Authorisation Holder:

(To be completed nationally)

This leaflet was last revised in
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The following information is intended for healthcare professionals only:

Administration:
Monitor carefully patients for signs and symptoms of hypersensitivity reactions during and following each administration of Ferrologic.

Ferrologic should only be administered when staff trained to evaluate and manage anaphylactic reactions is immediately available, in an environment where full resuscitation facilities can be assured. The patient should be observed for adverse effects for at least 30 minutes following each Ferrologic injection.

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).

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.