

Package leaflet: Information for the patient

Feristark™

50 mg iron/ml Dispersion for Injection/Infusion

ferric carboxymaltose

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.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

- 1. What Feristark is and what it is used for**
- 2. What you need to know before you receive Feristark**
- 3. How Feristark is administered**
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1. What Feristark is and what it is used for

Feristark is a medicine that contains iron.

Medicines that contain iron are used when you do not have enough iron in your body. This is called iron deficiency.

Feristark is used to treat iron deficiency when:

- oral iron is not effective enough
- you cannot tolerate oral iron
- your doctor decides you need iron very quickly to build up your iron stores.

The doctor will determine whether you have iron deficiency by performing a blood test.

2. What you need to know before you receive Feristark

You must not receive Feristark if you:

- are allergic (hypersensitive) to ferric carboxymaltose or any of the other ingredients of this medicine (listed in section 6)
- have experienced serious allergic (hypersensitive) reactions to other injectable iron preparations
- have anaemia **not** caused by iron deficiency
- have an iron overload (too much iron in your body) or disturbances in the utilisation of iron.

Warnings and precautions

Talk to your doctor or nurse before receiving Feristark if you:

- have a history of medicine allergy
- have systemic lupus erythematosus
- have rheumatoid arthritis
- have severe asthma, eczema or other allergies
- have an infection
- have liver disorders
- have or have had low levels of phosphate in the blood.

Incorrect administration of Feristark may cause leakage of the product at the administration site, which may lead to irritation of the skin and potentially long lasting brown discolouration at the site of administration. The administration must be stopped immediately when this occurs.

Children

Feristark should not be given to children under 1 year of age.

Other medicines and Feristark

Tell your doctor if you are using, have recently used or might use any other medicines, including medicines obtained without prescription. If Feristark is given together with oral iron preparations, then these oral preparations could be less efficient.

Pregnancy

There is limited data from the use of ferric carboxymaltose 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 Feristark. It is unlikely that Feristark represents a risk to the nursing child.

Driving and using machines

Feristark is unlikely to impair the ability to drive or operate machines.

Feristark contains sodium

Vial with 2 mL dispersion: This medicine contains less than 1 mmol sodium (23 mg) per vial, that is to say essentially 'sodium-free'.

Vial with 10 mL dispersion: This medicine contains up to 46 mg sodium (main component of cooking/table salt) in each vial. This is equivalent to 2.3% of the recommended maximum dietary daily intake of sodium for an adult.

Vial with 20 mL dispersion: This medicine contains up to 92 mg sodium (main component of cooking/table salt) in each vial. This is equivalent to equivalent to 4.6% of the recommended maximum daily dietary intake of sodium for an adult.

3. How Feristark is administered

Your doctor will decide how much Feristark to give you, how often you need it and for how long.

Your doctor will perform a blood test to determine the dose you need.

Adults and adolescents aged 14 years and older

Your doctor or nurse will administer Feristark undiluted by injection, diluted by infusion, or during dialysis,:

- By injection, you may receive up to 20 ml of Feristark, corresponding to 1,000 mg of iron, once a week directly into the vein.
- By infusion, you may receive up to 20 ml of Feristark, corresponding to 1,000 mg of iron, once a week directly into the vein. Because Feristark is diluted with sodium chloride solution for the infusion, it may have a volume of up to 250 ml and appear as a brown solution.
- If you are on dialysis, you may receive Feristark during a haemodialysis session via the dialyser.

Children and adolescents aged 1 to 13 years

Your doctor or nurse will administer Feristark undiluted by injection, or diluted by infusion:

- Your child will receive Feristark directly into the vein. It will appear as a brown solution.
- If your child is on dialysis, Feristark should not be administered.

Feristark 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.

If you receive more Feristark than you should

As this medicine will be given to you by trained medical staff it is not likely that you will be given too much of this medicine.

The following information is intended for healthcare professionals only:

Monitor patients carefully for signs and symptoms of hypersensitivity reactions during and following each administration of Feristark. Feristark 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 Feristark administration.

Step 1: Determination of the iron need

The individual iron need for repletion using Feristark is determined based on the patient's body weight and haemoglobin (Hb) level. Refer to Table 1 for determination of the total iron need. 2 doses may be required to replenish the total iron need, see Step 2 for the maximum individual iron doses.

Table 1: Determination of the total iron need

Hb		Patient body weight		
g/dL	mmol/L	Below 35 kg	35 kg to <70 kg	70 kg and above
<10	<6.2	30 mg/kg body weight	1,500 mg	2,000 mg
10 to <14	6.2 to <8.7	15 mg/kg body weight	1,000 mg	1,500 mg
≥14	≥8.7	15 mg/kg body weight	500 mg	500 mg

Step 2: Calculation and administration of the maximum individual iron dose(s)

Based on the total iron need determined above the appropriate dose(s) of Feristark should be administered taking into consideration the following:

Adults and adolescents aged 14 years and older

A single Feristark administration should not exceed:

- 15 mg iron/kg body weight (intravenous injection) or 20 mg iron/kg body weight (intravenous infusion)
- 1,000 mg of iron (20 ml Feristark)

The maximum recommended cumulative dose of Feristark is 1,000 mg of iron (20 ml Feristark) per week. If the total iron need is higher, then the administration of an additional dose should be a minimum of 7 days apart from the first dose.

Children and adolescents aged 1 to 13 years

A single Feristark administration should not exceed:

- 15 mg iron/kg body weight
- 750 mg of iron (15 mL Feristark)

The maximum recommended cumulative dose of Feristark is 750 mg of iron (15 ml Feristark) per week. If the total iron need is higher, then the administration of an additional dose should be a minimum of 7 days apart from the first dose.

Children below 1 year of age

Feristark is not recommended for use in children under 1 year of age.

Patients with haemodialysis-dependent chronic kidney disease

In adults and adolescents aged 14 years and older, a single maximum daily dose of 200 mg iron should not be exceeded in haemodialysis-dependent chronic kidney disease patients.

In children aged 1 to 13 years with chronic kidney disease requiring haemodialysis Feristark is not recommended for use.

Method of administration

Feristark must only be administered by the intravenous route: by injection, by infusion, or during a haemodialysis session undiluted directly into the venous limb of the dialyser. Feristark must not be administered by the subcutaneous or intramuscular route.

Inspect vials visually for sediment and damage before use. Use only those containing sediment-free, homogeneous dispersion. Each vial of Feristark is intended for single use only.

Caution should be exercised to avoid paravenous leakage when administering Feristark. Paravenous leakage of Feristark at the administration site may lead to irritation of the skin and potentially long lasting brown discolouration at the site of administration. In case of paravenous leakage, the administration of Feristark must be stopped immediately.

Intravenous injection

Feristark may be administered by intravenous injection using undiluted dispersion. In adults and adolescents aged 14 years and older, the maximum single dose is 15 mg iron/kg body weight but should not exceed 1,000 mg of

Overdose can cause accumulation of iron in your body. Your doctor will monitor iron parameters to avoid iron accumulation.

4. Possible side effects

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

Serious side effects:

Tell your doctor immediately if you experience any of the following signs and symptoms that may indicate a serious allergic reaction: rash (e.g. hives), itching, difficulty breathing, wheezing and/or swelling of the lips, tongue, throat or body, and chest pain which can be a sign of a potentially serious allergic reaction called Kounis syndrome.

In some patients these allergic reactions (affecting less than 1 in 1,000 people) may become severe or life-threatening (known as anaphylactic reactions) and can be associated with heart and circulation problems and loss of consciousness.

Tell your doctor if you develop worsening of tiredness, muscle or bone pain (pain in your arms or legs, joints or back). That may be a sign of a decrease in blood phosphorus which might cause your bones to become soft (osteomalacia). This condition may sometimes lead to bone fractures. Your doctor may also check the levels of phosphate in your blood, especially if you need a number of treatments with iron over time.

Your doctor is aware of these possible side effects and will monitor you during and after the administration of Feristark.

Other side effects that you should tell your doctor about if they become serious:

Common (may affect up to 1 in 10 people): headache, dizziness, feeling hot (flushing), high blood pressure, nausea and injection/infusion site reactions (see also section 2).

Uncommon (may affect up to 1 in 100 people):

numbness, tingling or prickling sensation on the skin, a change in your taste sensation, high heart rate, low blood pressure, difficulty breathing, vomiting, indigestion, stomach pain, constipation, diarrhoea, itching, hives, redness of the skin, rash, muscle-, joint -and/or back pain, pain in arms or legs, muscle spasms, fever, tiredness, chest pain, swelling of the hands and/or the feet, chills and a general feeling of discomfort.

Rare (may affect up to 1 in 1,000 people):

inflammation of a vein, anxiety, fainting, feeling faint, wheeze, excessive wind (flatulence), rapid swelling of the face, mouth, tongue or throat which may cause difficulty in breathing, paleness, and skin discoloration at other areas of the body than the administration site.

Not known (frequency cannot be estimated from the available data):

loss of consciousness and swelling of the face.

Flu-like illness (may affect up to 1 in 1,000 people) 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 muscles and joints.

Some blood parameters may change temporarily, which could be detected in laboratory tests.

The following change in blood parameters is common: decrease in blood phosphorus.

The following changes in blood parameters are uncommon: increase in certain liver enzymes called alanine aminotransferase, aspartate aminotransferase, gamma-glutamyltransferase and alkaline phosphatase, and increase in an enzyme called lactate dehydrogenase.

Ask your doctor for more information.

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 Yellow Card Scheme.

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Feristark

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 label. The expiry date refers to the last day of that month.

Do not store above 30°C. For storage conditions after dilution or first preparation of the vial for usage of the medicine, see section "The following information is intended for health care professionals only".

Feristark will normally be stored for you by your doctor or the hospital.

6. Contents of the pack and other information

What Feristark contains

The active substance is ferric carboxymaltose, an iron carbohydrate compound.

The concentration of iron present in the product is 50 mg per millilitre.

Each vial of 2 mL contains 100 mg iron (as ferric carboxymaltose).

Each vial of 10 mL contains 500 mg iron (as ferric carboxymaltose).

Each vial of 20 mL contains 1,000 mg iron (as ferric carboxymaltose).

The other ingredients are sodium hydroxide (for pH adjustment), hydrochloric acid (for pH adjustment), and water for injections.

What Feristark looks like and contents of the pack

Feristark is a dark brown, non-transparent dispersion for injection/infusion.

Feristark is supplied in glass vials containing:

- 2 ml dispersion. Available in pack sizes of 1, 2 and 5 vials.
- 10 ml dispersion. Available in pack sizes of 1, 2 and 5 vials.
- 20 ml dispersion. Available in a pack size of 1 vial.

Not all pack sizes may be marketed.

Marketing Authorisation Holder: Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX, United Kingdom

Manufacturer: PLIVA Hrvatska d.o.o. (PLIVA Croatia Ltd.), Prilaz baruna Filipovica 25, 10000 Zagreb, Croatia

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iron. In children aged 1 to 13 years, the maximum single dose is 15 mg iron/kg body weight but should not exceed 750 mg of iron. The administration rates are as shown in Table 2:

Table 2: Administration rates for intravenous injection of Feristark

Volume of Feristark required	Equivalent iron dose	Administration rate / Minimum administration time
2 to 4 ml	100 to 200 mg	No minimal prescribed time
>4 to 10 ml	>200 to 500 mg	100 mg iron/min
>10 to 20 ml	>500 to 1,000 mg	15 minutes

Intravenous infusion

Feristark may be administered by intravenous infusion, in which case it must be diluted. In adults and adolescents aged 14 years and older, the maximum single dose is 20 mg iron/kg body weight but should not exceed 1,000 mg of iron. In children aged 1 to 13 years, the maximum single dose is 15 mg iron/kg body weight but should not exceed 750 mg of iron.

For infusion, Feristark must only be diluted in sterile 0.9% m/V sodium chloride solution as shown in Table 3. Note: for stability reasons, Feristark should not be diluted to concentrations less than 2 mg iron/ml (not including the volume of the ferric carboxymaltose dispersion).

Table 3: Dilution plan of Feristark for intravenous infusion

Volume of Feristark required	Equivalent iron dose	Maximum amount of sterile 0.9% m/V sodium chloride solution	Minimum administration time
2 to 4 ml	100 to 200 mg	50 ml	No minimal prescribed time
>4 to 10 ml	>200 to 500 mg	100 ml	6 minutes
>10 to 20 ml	>500 to 1,000 mg	250 ml	15 minutes

Monitoring measures

Re-assessment should be performed by the clinician based on the individual patient's condition. The Hb level should be re-assessed no earlier than 4 weeks post final Feristark administration to allow adequate time for erythropoiesis and iron utilisation. In the event the patient requires further iron repletion, the iron need should be recalculated using Table 1 above.

Incompatibilities

The absorption of oral iron is reduced when administered concomitantly with parenteral iron preparations. Therefore, if required, oral iron therapy should not be started for at least 5 days after the last administration of Feristark.

Overdose

Administration of Feristark in quantities exceeding the amount needed to correct iron deficit at the time of administration may lead to accumulation of iron in storage sites eventually leading to haemosiderosis. Monitoring of iron parameters such as serum ferritin and transferrin saturation may assist in recognising iron accumulation. If iron accumulation has occurred, treat according to standard medical practice, e.g. consider the use of an iron chelator.

In-use stability

Shelf life after first preparation of the vial for usage:

From a microbiological point of view, unless the procedure for preparing the vial for usage precludes the risk of microbial contamination, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user.

Shelf life after dilution with sterile 0.9% m/V sodium chloride solution:

Chemical and physical in-use stability has been demonstrated for 24 hours at 15 to 25°C.

From a microbiological point of view the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 15 to 25°C, unless dilution has taken place in controlled and validated aseptic conditions.

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