Package leaflet: Information for the patient

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

What is in this leaflet

1. What Fercarbos is and what it is used for

Fercarbos 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.

Fercarbos 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 Fercarbos

You must not receive Fercarbos
– If you are allergic to ferric carboxymaltose 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 anaemia not caused by iron deficiency.
– If you 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 Fercarbos:
– If you have a history of medicine allergy.
– If you have systemic lupus erythematosus.
– If you have rheumatoid arthritis.
– If you have severe asthma, eczema or other allergies.
– If you have an infection.
– If you have liver disorders.
– If you have or have had low levels of phosphate in the blood.

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

Incorrect administration of Fercarbos 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.

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

Pregnancy
There is limited data from the use of Fercarbos 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 Fercarbos. It is unlikely that this medicine represents a risk to the nursing child. This medicine can be used during breast-feeding

Driving and using machines
Fercarbos has no or negligible influence on the ability to drive or operate machines.

Fercarbos contains sodium
This medicine contains up to 5.5 mg sodium (main component of cooking/table salt) in each mL of undiluted dispersion. This is equivalent to 0.3% of the recommended maximum daily dietary intake of sodium for an adult.

3. How Fercarbos is administered

Your doctor will decide how much of this medicine 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 Fercarbos undiluted by injection, during dialysis, or diluted by infusion:
- By injection, you may receive up to 20 mL of Fercarbos, corresponding to 1 000 mg of iron, once a week directly into the vein.
- By infusion, you may receive up to 20 mL of Fercarbos, corresponding to 1 000 mg of iron, once a week directly into the vein. Because this medicine is diluted with sodium chloride solution for the infusion, it may have a volume of up to 250 mL and will appear as a brown solution.
- If you are on dialysis, you may receive this medicine during a haemodialysis session via the dialyser.

Children and adolescents aged 1 to 13 years

Your doctor or nurse will administer Fercarbos undiluted by injection, or diluted by infusion:
- Your child will receive this medicine directly into the vein. It will appear as a brown solution.
- If your child is on dialysis, Fercarbos should not be administered.

Fercarbos 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 Fercarbos 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.
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 Fercarbos.

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 feetchills 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 discolouration 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 [To be completed nationally]. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Fercarbos

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. Do not freeze. For storage conditions after dilution or first opening of the medicine, see section "The following information is intended for healthcare professionals only".

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

6. Contents of the pack and other information

What Fercarbos contains

The active substance is ferric carboxymaltose, an iron carbohydrate compound. The concentration of iron present in the product is 50 mg per millilitre. The other ingredients are hydrochloric acid (for pH adjustment), sodium hydroxide (for pH adjustment) and water for injections.

What Fercarbos looks like and contents of the pack

Fercarbos 50 mg iron/ml dispersion for injection/infusion is an opaque dark brown colour aqueous dispersion filled in glass vial with rubber stopper and aluminium seal.

100 mg/2 mL available in pack sizes of 1, 2 or 5 vials.
500 mg/10 mL available in pack sizes of 1, 2 or 5 vials.
1 000 mg/20 mL available in a pack size of 1 vial.

Not all pack sizes may be marketed

Marketing Authorisation Holder
[To be completed nationally]

Manufacturer
[To be completed nationally]

This medicinal product is authorised in the Member States of the European Economic Area under the following names:
[To be completed nationally]

This leaflet was last revised in 2026-07-08.

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 Fercarbos. This treatment 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 Fercarbos administration.

Step 1: Determination of the iron need
The individual iron need for repletion using this medicine 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 the appropriate dose(s) of Fercarbos should be administered taking into consideration the following:

Adults and adolescents aged 14 years and older

A single Fercarbos 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 Fercarbos)

The maximum recommended cumulative dose of Fercarbos is 1 000 mg of iron (20 mL Fercarbos) 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 Fercarbos administration should not exceed:
- 15 mg iron/kg body weight
- 750 mg of iron (15 mL Fercarbos)

The maximum recommended cumulative dose of Fercarbos is 750 mg of iron (15 mL Fercarbos) 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
Fercarbos is not recommended for use in children below 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 is not recommended for use.

Method of administration

Fercarbos 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. Fercarbos must not be administered by the subcutaneous or intramuscular route.

Caution should be exercised to avoid paravenous leakage when administering Fercarbos. Paravenous leakage of Fercarbos 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 Fercarbos must be stopped immediately.

Intravenous injection

Fercarbos 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 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 Fercarbos

Volume of Fercarbos required	Equivalent iron dose	Administartion 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

Fercarbos 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, Fercarbos must only be diluted in sterile sodium chloride 9 mg/mL (0.9%) solution as shown in Table 3. Note: for stability reasons, Fercarbos 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 Fercarbos for intravenous infusion

Volume of Fercarbos required	Equivalent iron dose	Maximum amount of sterile sodium chloride 9 mg/mL (0.9%) 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 Fercarbos 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 Fercarbos.

Overdose

Administration of Fercarbos 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 opening of the container:

Chemical and physical in-use stability has been demonstrated for 7 days at 30°C.

From a microbiological point of view, unless the method of opening precludes the risk of microbial contamination, preparations for parenteral administration should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user. Administration of the product must be carried out under controlled and validated aseptic conditions.

Shelf-life in polyethylene and polypropylene containers after dilution with sterile sodium chloride 9 mg/mL (0.9%) solution:

Chemical and physical in-use stability of the diluted product has been demonstrated for 72 hours at 30°C at concentrations of 2 mg/mL and 5 mg/mL.

From a microbiological point of view, the diluted 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 2 to 8 ºC, unless the dilution has taken place in controlled and validated aseptic conditions.

Shelf life in polypropylene syringe (undiluted):

Chemical and physical in-use stability has been demonstrated for 72 hours at 30°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 2 to 8°C, unless the transfer to the syringe has taken place in controlled and validated aseptic conditions.