

Package leaflet: Information for the patient

Ferric carboxymaltose 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 Ferric carboxymaltose is and what it is used for
2. What you need to know before you use Ferric carboxymaltose
3. How Ferric carboxymaltose is administered
4. Possible side effects
5. How to store Ferric carboxymaltose
6. Contents of the pack and other information

1. What Ferric carboxymaltose is and what it is used for

Ferric carboxymaltose 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.

Ferric carboxymaltose 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 use Ferric carboxymaltose

You must not receive Ferric carboxymaltose

- if you are allergic (hypersensitive) 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 Ferric carboxymaltose:

- 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.

Incorrect administration of Ferric carboxymaltose 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 and adolescents

Ferric carboxymaltose should not be given to children under 14 years.

Other medicines and Ferric carboxymaltose

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

Pregnancy

There are 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 Ferric carboxymaltose. It is unlikely that Ferric carboxymaltose represents a risk to the nursing child.

Driving and using machines

Ferric carboxymaltose is unlikely to impair the ability to drive or operate machines.

Ferric carboxymaltose contains sodium.

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

Vial with 10 ml dispersion: This medicinal product contains maximum 59 mg sodium (main component of cooking/table salt) in each vial. This is equivalent to 2.95% of the recommended maximum daily dietary intake of sodium for an adult.

Vial with 20 ml dispersion: This medicinal product contains maximum 118 mg sodium (main component of cooking/table salt) in each vial, equivalent to 5.9% of the recommended maximum daily dietary intake of sodium for an adult.

3. How Ferric carboxymaltose is administered

Your doctor will decide how much Ferric carboxymaltose 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. Your doctor or nurse will administer Ferric carboxymaltose undiluted by injection, during dialysis, or diluted by infusion:

- By injection, you may receive up to 20 ml of Ferric carboxymaltose, corresponding to 1,000 mg of iron, once a week directly into the vein.
- If you are on dialysis, you may receive Ferric carboxymaltose during a haemodialysis session via the dialyser.

- By infusion, you may receive up to 20 ml of Ferric carboxymaltose, corresponding to 1,000 mg of iron, once a week directly into the vein. Because Ferric carboxymaltose 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.

Ferric carboxymaltose 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 Ferric carboxymaltose 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 anaphylactoid/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 Ferric carboxymaltose.

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, and chills

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

inflammation of a vein, a general feeling of discomfort, 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 for Ireland via the national reporting system: HPRA Pharmacovigilance; website: www.hpra.ie. For Malta, you can also report side effects via ADR Reporting Website: www.medicinesauthority.gov.mt/adrportal. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Ferric carboxymaltose

Keep Ferric carboxymaltose out of the sight and reach of children. Do not use Ferric carboxymaltose 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'.

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

6. Contents of the pack and other information

What Ferric carboxymaltose contains

The active substance is iron (as ferric carboxymaltose, an iron carbohydrate compound). One ml of dispersion contains 50 mg of iron (as ferric carboxymaltose).

The other ingredients are sodium hydroxide (for pH adjustment) (E524), hydrochloric acid, concentrated (E507) (for pH adjustment), and water for injection.

What Ferric carboxymaltose looks like and contents of the pack

Ferric carboxymaltose is a dark brown, non-transparent dispersion for injection/infusion. Ferric carboxymaltose is supplied in glass vials closed with a grey rubber stopper and aluminium flip cap containing:

- 2 ml dispersion corresponding to 100 mg iron. Available in pack sizes of 1, 2 and 5 vials.
- 10 ml dispersion corresponding to 500 mg iron. Available in pack sizes of 1, 2 and 5 vials.
- 20 ml dispersion corresponding to 1,000 mg iron. Available in a pack size of 1 vial.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturer

Lek Pharmaceuticals d.d., Verovškova ulica 57, 1526 Ljubljana, Slovenia.

This medicine is authorised in the Member States of the European Economic Area under the following names:

AT	Eisencarboxymaltose Sandoz 50 mg/ml - Dispersion zur Injektion/Infusion
BE	Ferric carboxymaltose Sandoz 50 mg ijzer/ml dispersie voor injectie/infusie
BG	XABOGARD КСАБОГАРД
DE	FerApplic 50 mg/ml Dispersion zur Injektion/Infusion
ES	Hierro carboximaltosa Sandoz 50 mg/ml solución inyectable y para perfusión EFG
FI	Xabogard 50 mg Fe/ml injektio-/infusioneste, liuos
HR	XABOGARD 50 mg/ml otopina za injekciju ili infuziju
IE	Ferric carboxymaltose 50 mg iron/ml dispersion for injection/infusion
IT	Carbossimaltosio ferrico Sandoz
MT	Ferric carboxymaltose 50 mg iron/ml dispersion for injection/infusion
NL	IJzer(III)carboxymaltose Sandoz 50 mg/ml, dispersie voor injectie/infusie
PT	Carboximaltose férrica Sandoz
RO	XABOGARD 50 mg fer/ml solutie injectabila/perfuzabila
SE	Xabogard 50 mg Fe/ml injektions-/infusionsvätska, lösning
SI	Xabogard 50 mg/ml disperzija za injiciranje/infundiranje
SK	Ferric carboxymaltose Sandoz 50 mg železa/ml injekčná/infúzna disperzia

This leaflet was last revised in 05/2023.

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 Ferric carboxymaltose. Ferric carboxymaltose 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 Ferric carboxymaltose administration.

Determination of the iron need

The individual iron need for repletion using Ferric carboxymaltose is determined based on the patient's body weight and haemoglobin (Hb) level (see Table 1):

Table 1: Determination of the 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	500 mg	1,500 mg	2,000 mg
10 to <14	6.2 to <8.7	500 mg	1,000 mg	1,500 mg
≥14	≥8.7	500 mg	500 mg	500 mg

Iron deficiency must be confirmed by laboratory tests.

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

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

A single Ferric carboxymaltose 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 Ferric carboxymaltose)

The maximum recommended cumulative dose of Ferric carboxymaltose is 1,000 mg of iron (20 ml Ferric carboxymaltose) per week.

A single maximum daily dose of 200 mg iron should not be exceeded in haemodialysis-dependent chronic kidney disease patients.

The use of Ferric carboxymaltose has not been studied in children, and therefore is not recommended in children under 14 years.

Method of administration

Inspect vials visually for sediment and damage before use. Use only those containing sediment-free, homogeneous dispersion.

Ferric carboxymaltose 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. Ferric carboxymaltose must not be administered by the subcutaneous or intramuscular route. Caution should be exercised to avoid paravenous leakage when administering Ferric carboxymaltose. Paravenous leakage of Ferric carboxymaltose 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 Ferric carboxymaltose must be stopped immediately.

Intravenous injection

Ferric carboxymaltose may be administered by intravenous injection using undiluted dispersion. The maximum single dose is 15 mg iron/kg body weight but should not exceed 1,000 mg iron. The administration rates are as shown in Table 2:

Table 2: Administration rates for intravenous injection of Ferric carboxymaltose

Volume of Ferric carboxymaltose	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	20 minutes

Intravenous infusion

Ferric carboxymaltose may be administered by intravenous infusion, in which case it must be diluted. The maximum single dose is 20 mg iron/kg body weight but should not exceed 1,000 mg iron. Ferric carboxymaltose must only be diluted in sterile 0.9% m/V sodium chloride solution as shown in Table 3. Note: for stability reasons, Ferric carboxymaltose 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 Ferric carboxymaltose for intravenous infusion

Volume of Ferric carboxymaltose	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	20 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 Ferric carboxymaltose 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 Ferric carboxymaltose.

Overdose

Administration of Ferric carboxymaltose 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 vial:

Chemical and physical in-use stability has been demonstrated for 7 days at room temperature (20 - 25°C).

From a microbiological point of view, 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 after dilution in polyethylene bottles (after dilution with sterile 0,9% m/V sodium chloride solution):

Chemical and physical in-use stability has been demonstrated for 24 hours at room temperature (20 - 25°C) at concentrations of: 2mg/ml, 4mg/ml and 5mg/ml.

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 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 24 hours at room temperature (20 - 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 2 to 8°C, unless preparation has taken place in controlled and validated aseptic conditions