Package leaflet: Information for the patient

Ferric Carboxymaltose Teva 50 mg iron/mL Dispersion for Injection/Infusion

iron as 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 Teva is and what it is used for

Ferric Carboxymaltose Teva 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 Teva 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 Ferric Carboxymaltose Teva

You must not receive Ferric Carboxymaltose Teva
- 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 Teva:
- 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 Teva 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
Ferric Carboxymaltose Teva should not be given to children under 1 year of age.

Other medicines and Ferric Carboxymaltose Teva
Tell your doctor if you are using, have recently used or might use any other medicines, including medicines obtained without prescription. If Ferric Carboxymaltose Teva 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 Ferric Carboxymaltose Teva. It is unlikely that Ferric Carboxymaltose Teva represents a risk to the nursing child.

Driving and using machines
Ferric Carboxymaltose Teva is unlikely to impair the ability to drive or operate machines.

Ferric Carboxymaltose Teva 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 dietery 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 dietery intake of sodium for an adult.

3. How Ferric Carboxymaltose Teva is administered

Your doctor will decide how much Ferric Carboxymaltose Teva 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 Ferric Carboxymaltose Teva undiluted by injection, diluted by infusion, or during dialysis:
- By injection, you may receive up to 20 mL of Ferric Carboxymaltose Teva, corresponding to 1,000 mg of iron, once a week directly into the vein.
- By infusion, you may receive up to 20 mL of Ferric Carboxymaltose Teva, corresponding to 1,000 mg of iron, once a week directly into the vein. Because Ferric Carboxymaltose Teva 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 Ferric Carboxymaltose Teva during a haemodialysis session via the dialyser.

Children and adolescents aged 1 to 13 years
Your doctor or nurse will administer Ferric Carboxymaltose Teva undiluted by injection, or diluted by infusion:
- Your child will receive Ferric Carboxymaltose Teva directly into the vein. It will appear as a brown solution.
- If your child is on dialysis, Ferric Carboxymaltose Teva should not be administered.

Ferric Carboxymaltose Teva 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 Teva 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 Ferric Carboxymaltose Teva

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 HPRA Pharmacovigilance website: www.hpra.ie.
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ferric Carboxymaltose Teva

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 30ºC. For storage conditions after dilution or first opening of the medicine, see section "The following information is intended for health care professionals only".

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

6. Contents of the pack and other information

What Ferric Carboxymaltose Teva 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 Ferric Carboxymaltose Teva looks like and contents of the pack
Ferric Carboxymaltose Teva is a dark brown, non-transparent dispersion for injection/infusion.

Ferric Carboxymaltose Teva 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 disperion. Available in a pack size of 1 vial.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Teva B.V, Swensweg 5, 2031GA, Haarlem, The Netherlands

Manufacturer

PLIVA Croatia Ltd. Prilaz baruna Filipovića 25, Zagreb, 10000, Croatia

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

AT (RMS)	Eisen-Carboxymaltose TEVA 50 mg Eisen/ml Dispersion zur Injektion/Infusion
BG	Максифер 50 mg/ml инжекционна/инфузионна дисперсия Maxifer 50 mg/ml dispersion for injection/infusion
CZ	Ferric carboxymaltose Teva
DE	Eisen(III)-Carboxymaltose AbZ 50 mg Eisen/ml Dispersion zur Injektion/Infusion
DK	Feriliva
EL	Ferric carboxymaltose/Teva
ES	CARBOXIMALTOSA FERRICA TEVA 50 MG/ML DISPERSION INYECTABLE Y PARA PERFUSIÓN EFG
FR	CARBOXYMALTOSE FERRIQUE TEVA 50mg/ml, dispersion injectable/pour perfusion
HR	Željezova karboksimaltoza Teva 50 mg/ml disperzija za injekciju ili infuziju
HU	Vas (III)-karboximaltóz Teva 50 mg/ml diszperziós injekció vagy infúzió
IE	Ferric carboxymaltose Teva 50 mg iron/ml dispersion for injection/infusion
IT	CARBOSSIMALTOSIO FERRICO TEVA
NL	IJzer(III)carboxymaltose Teva 50 mg/ml, dispersie voor injectie/infusie
NO	Feriliva
PT	Carboximaltose férrica Teva
RO	Carboximaltoză ferică Teva 50 mg/ml dispersie injectabilă/perfuzabilă
SE	Feriliva
SI	Železova karboksimaltoza Teva 50 mg/ml disperzija za injiciranje/infundiranje
SK	Ferric carboxymaltose Teva 50 mg/ml

This leaflet was last revised in {February 2024}.

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 Teva

Ferric Carboxymaltose Teva 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 Teva administration.

The posology of Ferric Carboxymaltose Teva follows a stepwise approach:

Step 1: Determination of the iron need
The individual iron need for repletion using Ferric Carboxymaltose Teva 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.

Iron deficiency must be confirmed by laboratory tests.

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 Ferric Carboxymaltose Teva should be administered taking into consideration the following:

Adults and adolescents aged 14 years and older
A single Ferric Carboxymaltose Teva administration should not exceed:
- 15 mg iron/kg body weight (for administration by intravenous injection) or 20 mg iron/kg body weight (for administration by intravenous infusion)
- 1,000 mg of iron (20 mL Ferric Carboxymaltose Teva

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

The maximum recommended cumulative dose of Ferric Carboxymaltose Teva is 750 mg of iron (15 mL Ferric Carboxymaltose Teva) 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.

Step 3: Post-iron repletion assessment
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 Teva 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 (see Step 1).

Children below 1 year of age
Ferric Carboxymaltose Teva is not recommended 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 Ferric Carboxymaltose Teva is not recommended.

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

Ferric Carboxymaltose Teva must only be administered by the intravenous route:
- by injection, or
- by infusion, or
- during a haemodialysis session undiluted directly into the venous limb of the dialyser.

Ferric Carboxymaltose Teva must not be administered by the subcutaneous or intramuscular route.

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

Intravenous injection
Ferric Carboxymaltose Teva 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 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 iron. The administration rates are as shown in Table 2:

Table 2: Administration rates for intravenous injection of Ferric Carboxymaltose Teva

Volume of Ferric Carboxymaltose Teva 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
Ferric Carboxymaltose Teva 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 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 iron.

For infusion, Ferric Carboxymaltose Teva must only be diluted in sterile 0.9% m/V sodium chloride solution as shown in Table 3. Note: for stability reasons, Ferric Carboxymaltose Teva 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 Teva for intravenous infusion

Volume of Ferric Carboxymaltose Teva 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

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 Teva

Overdose
Administration of Ferric Carboxymaltose Teva 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:
From a microbiological point of view, unless the method of opening 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.