PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

Ferric Teva

Dispersion for injection/infusion

50 mg iron/ml

The active ingredient and its concentration:

Each 1 ml of dispersion contains 50 mg iron (as ferric carboxymaltose)

For information regarding inactive ingredients and allergens, see section 2 "Important information about some of the ingredients of the medicine" and section 6 "Additional information".

Read the entire leaflet carefully before using the medicine.

This leaflet contains concise information about the medicine. If you have additional questions, refer to the doctor or the pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

For treatment of iron deficiency when oral iron preparations are ineffective or cannot be used.

The diagnosis must be based on laboratory tests.

Therapeutic class: iron, preparations for treatment of anemia.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You are sensitive (allergic) to ferric carboxymaltose or to any of the other components the medicine contains (see section 6).
- You have had a severe allergic reaction (hypersensitivity) to other injectable iron preparations.
- You have anemia that is not caused by iron deficiency.
- You have an excess of iron in your body or a problem in the way your body uses iron.

Special warnings regarding the use of the medicine

Before treatment with Ferric Teva, inform the doctor if you have:

- A history of sensitivity to medicines
- Systemic lupus erythematosus
- Rheumatoid arthritis
- Severe asthma, eczema or other allergies
- Any infection
- Liver problems
- Low levels of phosphate in the blood

Improper administration of Ferric Teva may cause leakage of the substance at the administration site, which may lead to irritation of the skin and even to long lasting discoloration of the skin at the administration site. In such cases, stop the administration immediately.

Children and adolescents

Do not give to children under 14 years of age.

Tests and follow-up

The doctor will refer you to blood tests in order to determine the required dosage of the medicine.

Drug interactions

If you are taking, or have recently taken, other medicines including non-prescription medicines and nutritional supplements, tell the doctor or the pharmacist. Especially if you are taking:

- Oral iron preparations, which may be less effective when given together with Ferric Teva.

Pregnancy, breastfeeding and fertility

Pregnancy – there is little information available regarding the use of Ferric Teva in pregnant women. It is important to inform the doctor if you are pregnant, think you are pregnant or are planning to become pregnant.

Consult the doctor if you become pregnant during the treatment. The doctor will determine whether or not you can continue to receive the medicine.

Breastfeeding – if you are breastfeeding, consult the doctor before treatment with Ferric Teva. Ferric Teva is unlikely to pose a risk to the breastfed child.

Driving and operating machinery

Ferric Teva is unlikely to impair the ability to drive or operate machinery.

Important information about some of the ingredients of the medicine

2 ml vial: contains less than 1 mmol of sodium (23 mg) per vial, therefore the medicine is considered sodium-free.

10 ml vial: contains 46 mg of sodium (the main component of cooking/table salt) per vial, which is equivalent to 2.3% of the recommended maximum daily intake for adults.

20 ml vial: contains 92 mg of sodium (the main component of cooking/table salt) per vial, which is equivalent to 4.6% of the recommended maximum daily intake for adults.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the doctor's instructions.

Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the preparation.

The dosage and treatment regimen will be determined only by the doctor.

The doctor or nurse will give you Ferric Teva undiluted by injection, during dialysis or after dilution by infusion:

- By injection directly into the vein, up to 20 ml Ferric Teva which is 1000 mg iron, once per week.
- During dialysis, Ferric Teva will be injected into the venous line of the dialysis machine.
- By direct intravenous infusion, up to 20 ml Ferric Teva which is 1000 mg iron, once per week. Since Ferric Teva is diluted in saline solution, the volume may reach up to 250 ml and the solution will have a brown color.

Ferric Teva will be administered in a clinic which has appropriate facilities for immediate treatment of allergic reactions.

After administration, you should remain under medical observation for 30 minutes.

Do not exceed the recommended dose.

If an overdose is administered by mistake

Since the medicine is administered by trained medical personnel, it is unlikely that a larger dose than required will be given.

An overdose may cause accumulation of iron in the body. The doctor will monitor iron parameters in order to prevent accumulation of iron.

4. SIDE EFFECTS

As with any medicine, using Ferric Teva may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

Severe side effects:

Inform the doctor immediately if you experience any of the following signs or symptoms which may indicate an allergic reaction:

- Rash (such as hives)
- Itch
- Breathing difficulties
- Wheezing
- Swelling of the lips, tongue, throat or body
- Chest pain which may be a sign of a serious allergic reaction called Kounis syndrome

In certain patients, these allergic reactions (which occur in 1-10 users out of 10,000) may be severe or life-threatening (known as anaphylactic reaction) and involve problems in the heart and circulatory system and loss of consciousness. Inform the doctor if you experience worsening of tiredness, muscle or bone pain (pain in the arms or legs, joints or back). This can be a sign of a decrease in blood phosphate levels which may cause softening of the bones (osteomalacia). This condition may sometimes lead to bone fractures. The doctor will check the levels of phosphate in your blood, especially if you need several iron treatments over time.

The doctor is aware of these possible side effects and will monitor your condition during and after treatment.

Additional side effects:

Common side effects – effects that occur in 1-10 out of 100 users:

- Headache
- Dizziness
- Heat sensation (flushing)
- High blood pressure
- Nausea
- Reactions at the site of administration (see also section 2)
- A transient decrease of phosphate levels in the blood

Uncommon side effects – effects that occur in 1-10 out of 1,000 users:

- Numbness
- Tingling or prickling sensation
- Altered sense of taste
- Rapid heartbeat
- Low blood pressure
- Breathing difficulties
- Vomiting, indigestion, abdominal pain, constipation, diarrhea
- Itch, hives, redness in the skin, rash
- Muscle, joint and/or back pain, pain in the arms or legs, muscle spasms
- Fever
- Tiredness
- Chest pain
- Swelling of the hands and/or feet
- Chills
- General feeling of discomfort
- A transient elevation of the liver enzymes alanine aminotransferase, aspartate aminotransferase, gamma glutamyl transferase, alkaline phosphatase and of the enzyme lactate dehydrogenase

Rare side effects – effects that occur in 1-10 users out of 10,000:

- Inflammation of the veins
- Anxiety
- Fainting, feeling faint
- Wheezing
- Flatulence
- Rapid swelling of the face, mouth, tongue or throat which may cause breathing difficulties
- Pallor
- Skin discoloration in areas other than the administration site
- A flu-like illness may occur several hours to several days after administration and is usually characterized by symptoms such as high fever and pain in the muscles and joints

Side effects with unknown frequency:

- Loss of consciousness
- Swelling of the face

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult your doctor.

Side effects may be reported to the Ministry of Health by clicking on the link "Report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following link: https://sideeffects.health.gov.il/

5. HOW TO STORE THE MEDICINE?

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
- Do not use the medicine after the expiry date (Exp.) appearing on the package. The expiry date refers to the last day of that month.
- Store at a temperature below 30°C.
- For storage instructions after dilution or after first opening the medicine, see the section "The following information is intended for healthcare professionals only".

6. ADDITIONAL INFORMATION

In addition to the active ingredient, the medicine also contains: Sodium hydroxide, Hydrochloric acid, Water for injection

What does the medicine look like and what are the contents of the package: 2, 10 or 20 ml glass vials, containing a dark brown dispersion.

Not all package sizes may be marketed.

Name and address of the manufacturer and license holder:

Teva Israel Ltd., 124 Dvora HaNevi'a St., Tel Aviv 6944020.

Revised in November 2024 in accordance with the Ministry of Health guidelines.

Registration number of the medicine in the national drug registry of the Ministry of Health:

178-05-37635-99

teva

המידע הבא מיועד לאנשי הצוות הרפואי בלבד:

المعلومات التالية مخصصة لأفراد الطاقم الطبي فقط:

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 Teva. Ferric 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 Teva administration.

Step 1: Determination of the iron need

The individual iron need for repletion using Ferric Teva is determined based on the patient's body weight and hemoglobin (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 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

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 Teva should be administered taking into consideration the following:

A single Ferric Teva 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 Teva)

The maximum recommended cumulative dose of Ferric Teva is 1,000 mg of iron (20 mL Ferric 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.

Patients with hemodialysis-dependent chronic kidney disease

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

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

Method of administration

Ferric Teva must only be administered by the intravenous route: by injection, by infusion, or during a hemodialysis session undiluted directly into the venous limb of the dialyzer. Ferric Teva must not be administered by the subcutaneous or intramuscular route.

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

Intravenous injection

Ferric Teva 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 Teva

Volume of Ferric 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 Teva 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 of iron.

For infusion, Ferric Teva must only be diluted in sterile 0.9% m/V sodium chloride solution as shown in Table 3.

Note: for stability reasons, Ferric 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 Teva for intravenous infusion

Volume of Ferric 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

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 Teva administration to allow adequate time for erythropoiesis and iron utilization. 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 Teva.

Overdose

Administration of Ferric 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 hemosiderosis.

Monitoring of iron parameters such as serum ferritin and transferrin saturation may assist in recognizing 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.