FERINJECT®

1. NAME OF THE MEDICINAL PRODUCT

Ferinject 50 mg iron/ml solution for injection/infusion.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One ml of solution contains 50 mg of iron as ferric carboxymaltose.

Each 2 ml vial contains 100 mg of iron as ferric carboxymaltose.
Each 10 ml vial contains 500 mg of iron as ferric carboxymaltose.

Excipient(s) with known effect
One ml of solution contains up to 5.5 mg (0.24 mmol) sodium, see section 4.4. For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection/infusion. Dark brown, non-transparent, aqueous solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Ferinject is indicated for the treatment of iron deficiency when (see section 5.1)
-oral iron preparations are ineffective.
-oral iron preparations cannot be used.
-there is a clinical need to deliver iron rapidly

The diagnosis must be based on laboratory tests.

4.2 Posology and method of administration

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

Ferinject 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 closely observed for signs and sympotms of hypersensitivity reactions during and for at least 30 minutes following each Ferinject administration .

Posology

The posology of Ferinject follows a stepwise approach: [1] determination of the individual iron need, [2] calculation and administration of the iron dose(s), and [3] post-iron repletion assessments. These steps are outlined below:

Step 1: Determination of the iron need
The individual iron need for repletion using Ferinject is determined based on the patient's body weight and haemoglobin (Hb) level. Refer to Table 1 for determination of the iron need:

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 as stated in 4.1.

Step 2: Calculation and administration of the maximum individual iron dose(s)
Based on the iron need determined above the appropriate dose(s) of Ferinject should be administered taking into consideration the following:

A single Ferinject 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 Ferinject)

The maximum recommended cumulative dose of Ferinject is 1,000 mg of iron (20 mL Ferinject) per week.

Step 3: Post-iron repletion assessments
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 Ferinject 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. (See section 5.1.)

Special Population – patients with haemodialysis-dependent chronic kidney disease
A single maximum daily dose of 200 mg iron should not be exceeded in haemodialysis-dependent chronic kidney disease patients (see also section 4.4).

Paediatric population
The use of Ferinject has not been studied in children, and therefore is not recommended in children under 14 years.

Method of administration

Ferinject 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.

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

Intravenous Injection
Ferinject must be administered only by the intravenous injection using undiluted solution.

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 Ferinject

Volume of Ferinject 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
Ferinject 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.

For infusion, Ferinject must only be diluted in sterile 0.9% m/V sodium chloride solution as shown in Table 3. Note: for stability reasons, Ferinject should not be diluted to concentrations less than 2 mg iron/mL (not including the volume of the ferric carboxymaltose solution). For further instructions on dilution of the medicinal product before administration, see section 6.6.

Table 3: Dilution plan of Ferinject for intravenous infusion

Ferinject			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	100ml	6 minutes
>10	to	20 ml	>500	to	1000 mg	250 ml	15 minutes

4.3 Contraindications

The use of Ferinject is contraindicated in cases of:
- Hypersensitivity to ferric carboxymaltose complex, to ferric carboxymaltose solution or to any of its excipients listed in section 6.1
- anaemia not attributed to iron deficiency, e.g. other microcytic anaemia
- evidence of iron overload or disturbances in utilisation of iron

4.4 Special warnings and precautions for use

Hypersensitivity reactions
Parenterally administered iron preparations can cause hypersensitivity reactions including anaphylactoid reactions, which may be fatal (see section 4.8). Therefore, facilities for cardio-pulmonary resuscitation must be available. If hypersensitivity reactions or signs of intolerance occur during administration, the treatment must be stopped immediately. Hypersensitivity reactions have also been reported after previously uneventful doses of any parenteral iron complexes, including ferric carboxymaltose. There have been reports of hypersensitivity reactions which progressed to Kounis syndrome (acute allergic coronary arteriospasm that can result in myocardial infarction, see section 4.8).

Hypophosphataemia / Hypophosphataemic osteomalacia
Parenterally iron preparations can lead to hypophosphataemia which is transient and without clinical symptoms in most cases. Hypophosphatemia requiring treatment has mainly been reported in individual cases, in patients with known risk factors and after sustained higher dosing.

Cases of symptomatic hypophosphataemia leading to hypophosphataemic osteomalacia, and fractures requiring clinical intervention, including surgery, were reported after market introduction. In case of arthralgia or bone pain, patients should be advised to seek medical advice.

Patients receiving multiple higher doses as part of long-term treatment, and who have underlying risk factors (e.g. vitamin D deficiency, calcium and phosphate malabsorption, secondary hyperparathyroidism, hereditary haemorrhagic telangiectasia, inflammatory bowel disease and osteoporosis) should be monitored for hypophosphataemic osteomalacia, including serum phosphate control. In case of persistent hypophosphataemia, treatment with Ferinject should be re-evaluated.

Hepatic or renal impairment
In patients with liver dysfunction, parenteral iron should only be administered after careful risk/benefit assessment. Parenteral iron administration should be avoided in patients with hepatic dysfunction where iron overload is a precipitating factor, in particular Porphyria Cutanea Tarda (PCT). Careful monitoring of iron status is recommended to avoid iron overload.

No safety data on haemodialysis-dependent chronic kidney disease patients receiving single doses of more than 200 mg iron are available.

Infection
Parenteral iron must be used with caution in case of acute or chronic infection, or in patients with a history of asthma, eczema other atopic allergies or allergic reactions to other parenteral iron preparations, as they are particularly at risk of an allergic reaction. It is recommended that the administration of Ferinject is stopped in patients with ongoing bacteraemia. In patients with chronic infection a risk/benefit evaluation has to be performed, taking into account the suppression of erythropoiesis.

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

Excipients
One ml of undiluted Ferinject contains up to 5.5 mg (0.24 mmol) of sodium. This has to be taken into account in patients on a sodium-controlled diet.

*Paediatric population*The use of Ferinject has not been studied in children.

Do not administer 20 ml (1000 mg of iron) as an injection or infusion more than once a week.

4.5 Interaction with other medicinal products and other forms of interaction

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

4.6 Fertility, pregnancy and lactation

Pregnancy
There are limited clinical data from the use of Ferinject in pregnant women. A careful risk/benefit evaluation is required before use during pregnancy and Ferinject should not be used during pregnancy unless clearly necessary.
Iron deficiency occurring in the first trimester of pregnancy can in many cases be treated with oral iron. If the benefit of Ferinject treatment is judged to outweigh the potential risk to the fetus, it is recommended that treatment should be confined to the second and third trimester.

Foetal bradycardia may occur following administration of parenteral irons. It is usually transient and a consequence of a hypersensitivity reaction in the mother. The unborn baby should be carefully monitored during intravenous administration of parenteral irons to pregnant women.

Animal data suggest that iron released from Ferinject can cross the placental barrier and that its use during pregnancy may influence skeletal development in the fetus (see section 5.3).

Lactation
Clinical studies showed that transfer of iron from Ferinject to human milk was negligible (≤1%). Based on limited data on nursing women it is unlikely that Ferinject represents a risk to the nursing child.

Fertility
There are no data on the effect of Ferinject on human fertility. Fertility was unaffected following Ferinject treatment in animal studies (see section 5.3).

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

Adverse drug reactions reported in subjects (n> 8,000) from clinical trials as well as those reported from the post –marketing experience are summarised in the table below.

The most commonly reported ADR is nausea, occurring in 2.9% of the subjects ,followed by injection/infusion site reactions, hypophosphataemia, headache, flushing, dizziness and hypertension. Injection/infusion site reactions comprise several ADRs which individually are either uncommon or rare.

For subjects in clinical trials that showed a decrease in serum phosphorous, the minimum values were obtained after approximately 2 weeks, and in most cases returned to baseline values by 12 weeks following Ferinject treatment . The most serious ADR is anaphylactoid/anaphylactic reactions (rare); fatalities have been reported. See section 4.4 for further details.

System Organ Class	**Common (≥1/100, <1/10)**	**Uncommon (≥1/1000, <1/100)**	**Rare (≥1/10000, <1/1000)**	**Frequency not known**(1)

Immune system disorders		Hypersensitivity	Anaphylactoid/anaphylactic reactions	
Metabolism and Nutritional Disorders	Hypophosphataemia			
Nervous system disorders	Headache, dizziness	Paraesthesia, dysgeusia		Loss of consciousness[1]
Psychatric Disorders			Anxiety[2]	
Cardiac disorders		Tachycardia		Kounis syndrome[1]
Vascular disorders	Flushing,hypertension	Hypotension	Phlebitis, syncope[2], presyncope[2]	
Respiratory, thoracic and mediastinal disorders		Dyspnoea	Bronchospasm[2]	
Gastrointestinal disorders	Nausea	Vomiting, dyspepsia, abdominal pain, constipation, diarrhoea	Flatulence	
Skin and subcutaneous tissue disorders		Pruritus, urticaria, erythema, rash[3]	Angioedema[2], pallor[2] distant skin discoloration	Face oedema[1] dermatitis
Musculoskeletal and connective tissue disorders		Myalgia, back pain, arthralgia, pain in extremity, muscle spasms		Hypophosphataemic, osteomalacia [1]
General disorders and administration site conditions	Injection/infusion Site Reactions[4]	Pyrexia, fatigue, chest pain, oedema peripheral, pain, chills	Malaise, influenza like illness(whose onset may vary from a few hours to a few days)[2]	
Investigations		Alanine aminotransferase increased ,aspartate aminotransferase increased, gamma-glutamyltransferase increased, blood lactate dehydrogenase increased, blood alkaline phosphatase increased		

1: ADRs exclusively reported in the post-marketing setting; estimated as rare
2:ADRs reported in the post-marketing setting which are also observed in the clinical setting.
3: Includes the following preferred terms: rash (individual ADR determined to be uncommon) and rash erythematous, -generalised, -macular, -maculo-papular, -pruritic (all individual ADRs determined as rare).
4 Includes but is not limited to the following preferred terms: injections/infusions site, pain,haematoma , discolouration, extravasation, irritation, reaction, (all individual ADRs determined as uncommon) and paraesthesia (individual ADR determined as rare).
Note: ADR = Adverse drug reaction.

4.9 Overdose

Administration of Ferinject 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, the use of an iron chelator may be considered.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Iron trivalent, parenteral preparation

ATC Code: B03A C

Mechanism of action
Ferinject solution for injection/infusion is a colloidal solution of ferric carboxymaltose. It contains iron in a stable ferric state as a non-dextran iron complex consisting of a polynuclear iron-hydroxide core with a carbohydrate ligand. Because of the high stability of the complex, there is only a very small amount of weakly-bound iron (also called labile or free iron). The structure of the core of ferric carboxymaltose is similar to that of ferritin, the physiological iron storage protein. The complex is designed to provide, in a controlled way, utilisable iron for the iron transport and storage proteins in the body (transferrin and ferritin, respectively). Positron Emission Tomography (PET) showed that red cell utilisation of ^{59}Fe from radio-labelled ferric carboxymaltose ranged from 91% to 99% in subjects with iron deficiency and 61% to 84% in subjects with renal anaemia at 24 days post-dose. Ferinject treatment led to a clear increase in reticulocyte count indicating the increased saturation of erythrocyte precursor cells as iron becomes available. Serum ferritin levels and TSAT levels increasing to the normal range confirmed replenishment of the iron stores.

Clinical studies have shown that the haematological response and the filling of the iron stores is faster after intravenous administration of ferric carboxymaltose than with orally administered comparators.

Clinical efficacy and safety
Clinical efficacy studies have been conducted in numerous aetiologies that are representative of underlying diseases that may lead to iron deficiency, i.e., diseases with increased inflammatory status that may impair iron absorption, as well as indications with large losses of iron that cannot be compensated via dietary or oral iron. A brief summary of the key studies has been provided below.

Cardiology

Chronic heart failure

Study CONFIRM-HF was a double-blind, randomised, 2-arm study comparing Ferinject (n=150) vs. placebo (n=151) in subjects with chronic heart failure and ID for a treatment period of 52 weeks. At Day 1 and Week 6 (correction phase), subjects received either Ferinject according to a simplified dosing grid using baseline Hb and body weight at screening (see section 4.2), placebo or no dose. At Weeks 12, 24, and 36 (maintenance phase) subjects received Ferinject (500 mg iron) or placebo if serum ferritin was <100 ng/mL or 100-300 ng/mL with TSAT <20%. The treatment benefit of Ferinject vs. placebo was demonstrated with the primary

efficacy endpoint, the change in the 6-minute walk test (6MWT) from baseline to Week 24 (33±11 metres, p=0.002). This effect was sustained throughout the study to Week 52 (36±11 metres, p<0.001).

Study EFFECT-HF was an open-label (with blinded endpoint evaluation), randomised, 2-arm study comparing Ferinject (n=86) vs. standard of care (n=86) in subjects with chronic heart failure and ID for a treatment period of 24 weeks. At Day 1 and Week 6 (correction phase), subjects received either Ferinject according to a simplified dosing grid using baseline Hb and body weight at screening (see section 4.2) or standard of care. At Week 12, (maintenance phase) subjects received Ferinject (500 mg iron) or standard of care if serum ferritin <100 ng/ml or 100 to 300 ng/ml and TSAT <20%. The treatment benefit of Ferinject vs. standard of care was demonstrated with the primary efficacy endpoint, the change in weight-adjusted peak VO_2 from baseline to Week 24 (LS Mean 1.04 ±0.44 , p=0.02).

Nephrology

Four Phase 3 studies have been conducted in **nephrology**.

Haemodialysis-dependent chronic kidney disease
In a study of haemodialysis patients (VIT-IV-CL-015), the primary response rate, defined as an increase in Hb of at least 1 g/dL at 4 weeks after baseline, was 46.4% in the ferric carboxymaltose group and 37.2% in the Venofer® group.

Non-dialysis-dependent chronic kidney disease
In a pre-dialysis chronic kidney disease population (1VIT04004), 1 to 3 doses of ferric carboxymaltose (over 2 to 4 weeks) was shown more effective than 8 weeks of three times daily (TID) oral iron therapy across all primary and secondary ranked efficacy endpoints, and a statistically significant (p<0.001) greater proportion of subjects in the ferric carboxymaltose group (60.4%) compared to the ferrous sulphate group (34.7%) achieved an increase in Hb ≥1 g/dL. In a 44-week long-term extension to this study (1VIT05005), the efficacy of ongoing maintenance dosing with ferric carboxymaltose was demonstrated with primary endpoint (defined as Hb ≥11.0 g/dL, ferritin 100-800 ng/mL, and TSAT 30-50% on the same visit) achieved by 51.4% of patients overall. In another study including over 400 pre-dialysis patients (1VIT07018), the safety and efficacy of a single bolus injection (≤1,000 mg iron) of ferric carboxymaltose was compared to 30 days of standard medical care. The mean increases from baseline to end of study for Hb (0.54 g/dL), ferritin (294.28 ng/mL), and TSAT (10.01%) in the ferric carboxymaltose group were statistically significantly (p≤0.009) greater than those observed in the standard medical care group (0.31 g/dL, 109.72 ng/mL, and 4.87%, respectively).

Gastroenterology

Inflammatory bowel disease
In a population with **inflammatory bowel disease** the correction of iron deficiency anaemia via administration of ferric carboxymaltose was observed. In VIT-IV-CL-008, short treatment with ferric carboxymaltose (1 to 2 weeks) was shown to be non-inferior to 12 weeks of twice daily (BID) oral iron therapy: the mean increase in Hb from baseline to Week 12 was 3.83 g/dL in the ferric carboxymaltose group and 3.75 g/dL oral iron group. In the FER-IBD-07-COR study, a simplified dosing schedule (based on Hb and body weight) for ferric carboxymaltose was significantly more effective in improving anaemia by Week 12 compared to Venofer administered per Ganzoni formula. The percentage of responders achieving a Hb increase ≥2 g/dL at Week 12 was 66.06% in the ferric carboxymaltose group and 54.14% in the Venofer group (p=0.008), and 83.77% of ferric carboxymaltose patients (versus 75.91%

Venofer) achieved a Hb increase ≥2 g/dL or had Hb within World Health Organisation defined normal limits at Week 12 (p=0.019).

Women's health

Post partum
In **gynaecology**, 3 studies in post-partum patients and 1 study in patients with heavy uterine bleeding, 1 to 3 doses of ferric carboxymaltose were compared to oral ferrous sulphate 3 times daily for 6 weeks (1VIT06011, 1VIT03001, 1VIT04002/04003) or twice daily for 12 weeks (VIT-IV-CL-009). In post-partum study 1VIT06011, the proportion of patients achieving a Hb level >12 g/dL was statistically significantly (p<0.0001) greater in the ferric carboxymaltose group (91.4%) compared to the ferrous sulphate group (66.7%). In the latter 2 post-partum studies, non-inferiority of ferric carboxymaltose compared to oral iron was demonstrated for the primary Hb endpoints: In study 1VIT03001, the proportion of subjects achieving an increase in Hb levels of ≥2.0 g/dL was 96.4% in the ferric carboxymaltose group and 94.1% in the ferrous sulphate group. In study (VIT-IV-CL-009), the mean change in Hb from baseline to Week 12 was 3.37 g/dL in the ferric carboxymaltose group and 3.29 g/dL in the oral iron group. In the heavy uterine bleeding study 1VIT04002/04003) the proportion of patients who achieved an increase in Hb of ≥2.0 g/dL was statistically significantly (p<0.001) greater in the ferric carboxymaltose group (82.0%) compared with the oral ferrous sulphate group (61.8%).

In another study including over 2,000 patients with either heavy uterine bleeding or post-partum iron deficiency anaemia (1VIT07017), the safety and efficacy of a single bolus injection (≤1,000 mg iron) of ferric carboxymaltose was compared to standard medical care. A statistically significantly greater proportion of subjects in the ferric carboxymaltose group (68.1%) achieved an Hb value >12 g/dL compared to subjects in the standard medical care group (50.7%) who received oral iron.

Pregnancy
Intravenous iron medicines should not be used during pregnancy unless clearly necessary. Treatment with Ferinject should be confined to the second and third trimester if the benefit is judged to outweigh the potential risk for both the mother and the foetus, see section 4.6.

Limited safety data in pregnant women are available from study FER-ASAP-2009-01, a randomised, open-label study comparing Ferinject (n=121) vs. oral ferrous sulphate (n=115) in pregnant women in the second and third trimester with ID anaemia for a treatment period of 12 weeks. Subjects received Ferinject in cumulative doses of 1,000 mg or 1,500 mg of iron (mean cumulative dose: 1,029 mg iron) based on Hb and body weight at screening, or 100 mg of oral iron BID for 12 weeks. The incidence of treatment-related adverse events was similar between Ferinject treated women and those treated with oral iron (11.4% Ferinject group; 15.3% oral iron group). The most commonly reported treatment-related adverse events were nausea, upper abdominal pain and headache. Newborn Apgar scores as well as newborn iron parameters were similar between treatment groups.

5.2 Pharmacokinetic properties

Distribution
Using positron emission tomography (PET) it was demonstrated that ^{59}Fe and ^{52}Fe from Ferinject was rapidly eliminated from the blood, transferred to the bone marrow, and deposited in the liver and spleen.

After administration of a single dose of Ferinject of 100 to 1000 mg of iron in iron deficient patients, maximum total serum iron levels of 37 µg/ml up to 333 µg/ml after 15 minutes to 1.21 hours respectively are obtained. The volume of the central compartment corresponds well to the volume of the plasma (approximately 3 litres).

Elimination
The iron injected or infused was rapidly cleared from the plasma, the terminal half-life ranged from 7 to 12 hours, the mean residence time (MRT) from 11 to 18 hours. Renal elimination of iron was negligible.

5.3 Pre-clinical safety data

Pre-clinical data revealed no special hazard for humans based on conventional studies of safety pharmacology, repeat dose toxicity and genotoxicity. Pre-clinical studies indicate that iron released from Ferinject does cross the placental barrier and is excreted in milk in limited, controlled amounts. In reproductive toxicology studies using iron replete rabbits Ferinject was associated with minor skeletal abnormalities in the fetus. In a fertility study in rats, there were no effects on fertility for either male or female animals. No long-term studies in animals have been performed to evaluate the carcinogenic potential of Ferinject. No evidence of allergic or immunotoxic potential has been observed. A controlled in-vivo test demonstrated no cross-reactivity of Ferinject with anti-dextran antibodies. No local irritation or intolerance was observed after intravenous administration.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium hydroxide (for pH adjustment)
Hydrochloric acid (for pH adjustment)
Water for injections

6.2 Incompatibilities

This medicinal product must not be mixed with other medicinal products except those mentioned in section 6.6.
The compatibility with containers other than polyethylene and glass is not known.

6.3 Shelf-life

Shelf-life of the product as packaged for sale:
3 years.

Shelf-life after first opening of the container:
From a microbiological point of view, preparations for parenteral administration should be used immediately.

Shelf-life after dilution with sterile 0.9% m/V sodium chloride solution:
From a microbiological point of view, preparations for parenteral administration should be used immediately after dilution with sterile 0.9% m/V sodium chloride solution.

6.4 Special precautions for storage

Store in the original package. Do not store above 30 °C. Do not freeze.For storage conditions after dilution or first opening of the medicinal product, see section 6.3.

6.5 Nature and contents of container

2 ml of solution in a vial (type I glass) with bromobutyl rubber stopper and aluminium cap in pack size of 1 vial.

10 ml of solution in a vial (type I glass) with bromobutyl rubber stopper and aluminium cap in pack size of 1 vial.

6.6 Special precautions for disposal and other handling

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

Each vial of Ferinject is intended for single use only. Any unused product or waste material should be disposed of in accordance with local requirements.

Ferinject must only be mixed with sterile 0.9% m/V sodium chloride solution. No other intravenous dilution solutions and therapeutic agents should be used, as there is the potential for precipitation and/or interaction. For dilution instructions, see section 4.2.

7. PRODUCT OWNER

Vifor (International) Inc., Rechenstrasse 37, 9014 St Gallen Switzerland

8. MARKETING AUTHORISATION NUMBER

SIN14035P

9. DATE OF FIRST AUTHORISATION OF THE AUTHORISATION

Date of first authorisation: 19.10.2011

10. DATE OF REVISION OF THE TEXT

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