▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See section 4.8 for how to report adverse reactions.

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 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 the 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 of iron deficiency 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 observed for adverse effects for at least 30 minutes following each Ferinject administration (see section 4.4).

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 may be administered by 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

Volume of Ferinject 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

4.3 Contraindications

The use of Ferinject is contraindicated in cases of:

- hypersensitivity to the active substance, to Ferinject or any of its excipients listed in section 6.1.
- known serious hypersensitivity to other parenteral iron products.
- anaemia not attributed to iron deficiency, e.g. other microcytic anaemia.
- evidence of iron overload or disturbances in the utilisation of iron.

4.4 Special warnings and precautions for use

Hypersensitivity reactions
Parenterally administered iron preparations can cause hypersensitivity reactions including serious and potentially fatal anaphylactic/anaphylactoid reactions. Hypersensitivity reactions have also been reported after previously uneventful doses of parenteral iron complexes. 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).

The risk is enhanced for patients with known allergies including drug allergies, including patients with a history of severe asthma, eczema or other atopic allergy.
There is also an increased risk of hypersensitivity reactions to parenteral iron complexes in patients with immune or inflammatory conditions (e.g. systemic lupus erythematosus, rheumatoid arthritis).

Ferinject should only be administered when staff trained to evaluate and manage anaphylactic reactions are immediately available, in an environment where full resuscitation facilities can be assured. Each patient should be observed for adverse effects for at least 30 minutes following each Ferinject administration. If hypersensitivity reactions or signs of intolerance occur during administration, the treatment must be stopped immediately. Facilities for cardio respiratory

resuscitation and equipment for handling acute anaphylactic/anaphylactoid reactions should be available, including an injectable 1:1000 adrenaline solution. Additional treatment with antihistamines and/or corticosteroids should be given as appropriate.

Hypophosphataemic osteomalacia
Symptomatic hypophosphataemia leading to osteomalacia and fractures requiring clinical intervention including surgery has been reported in the post marketing setting. Patients should be asked to seek medical advice if they experience worsening fatigue with myalgias or bone pain. Serum phosphate should be monitored in patients who receive multiple administrations at higher doses or long-term treatment, and those with existing risk factors for hypophosphataemia. In case of persisting hypophosphataemia, treatment with ferric carboxymaltose should be re-evaluated.

Hepatic or renal impairment
In patients with liver dysfunction, parenteral iron should only be administered after careful benefit/risk 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, asthma, eczema or atopic allergies. It is recommended that the treatment with Ferinject is stopped in patients with ongoing bacteraemia. Therefore, in patients with chronic infection a benefit/risk 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 irritation of the skin and potentially long lasting brown discolouration 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.

4.5 Interaction with other medicinal products and other forms of interaction

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 Ferinject.

4.6 Fertility, pregnancy and lactation

Pregnancy
There are limited data from the use of Ferinject in pregnant women (see section 5.1). A careful benefit/risk 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. 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.

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).

Breast-feeding
Clinical studies showed that transfer of iron from Ferinject to human milk was negligible (≤1%). Based on limited data on breast-feeding women it is unlikely that Ferinject represents a risk to the breast-fed 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 and use machines.

4.8 Undesirable effects

Table 4 presents the adverse drug reactions (ADRs) reported during clinical studies in which >8,000 subjects received Ferinject, as well as those reported from the post-marketing experience (see table footnotes for details).

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.
The most serious ADR is anaphylactoid/anaphylactic reactions (rare); fatalities have been reported. See section 4.4 for further details.

Table 4: Adverse drug reactions observed during clinical trials and post-marketing experience

System Organ Class	Common (≥1/100 to <1/10)	Uncommon (≥1/1,000 to <1/100)	Rare (≥1/10,000 to <1/1,000)	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
Psychiatric 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)]	

System Organ Class	Common (≥1/100 to <1/10)	Uncommon (≥1/1,000 to <1/100)	Rare (≥1/10,000 to <1/1,000)	Frequency not known[1]
Gastrointestinal disorders	Nausea	Vomiting, dyspepsia, abdominal pain, constipation, diarrhoea	Flatulence	
Skin and subcutaneous tissue disorders		Pruritus, urticaria, erythema, rash[3]	Angioedema[2], pallor[2], ,	Face oedema[1]
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, chills	Malaise, influenza like illness (whose onset may vary from a few hours to several 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 to be rare).
4 Includes, but is not limited to, the following preferred terms: injection/infusion site -pain, -haematoma, -discolouration, -extravasation, -irritation, -reaction, (all individual ADRs determined to be uncommon) and -paraesthesia (individual ADR determined to be rare).
Note: ADR = Adverse drug reaction.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via E-mail: THZP-PV-Contact@zuelligpharma.com

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, treat according to standard medical practice, e.g. consider the use of an iron chelator.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Iron trivalent, parenteral preparation, ATC code: B03AC

Ferinject solution for injection/infusion is a colloidal solution of the iron complex ferric carboxymaltose.
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).
Red cell utilisation of ^{59}Fe from radio-labelled Ferinject ranged from 91% to 99% in subjects with iron deficiency (ID) and 61% to 84% in subjects with renal anaemia at 24 days post-dose.
Ferinject treatment of patients with ID anaemia results in an increase in reticulocyte count and serum ferritin levels to within normal ranges.

Clinical efficacy and safety

The efficacy and safety of Ferinject has been studied in different therapeutic areas necessitating intravenous iron to correct iron deficiency. The main studies are described in more detail 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 (33 ±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

Haemodialysis-dependent chronic kidney disease
Study VIT-IV-CL-015 was an open-label, randomised parallel group study comparing Ferinject (n=97) to iron sucrose (n=86) in subjects with ID anaemia undergoing haemodialysis. Subjects received Ferinject or iron sucrose 2-3 times per week in single doses of 200 mg iron directly into the dialyser until the individually calculated cumulative iron dose was reached (mean cumulative dose of iron as Ferinject: 1,700 mg). The primary efficacy endpoint was the percentage of subjects reaching an increase in Hb of ≥1.0 g/dL at 4 weeks after baseline. At 4 weeks after baseline, 44.1% responded to treatment with Ferinject (i.e. Hb increase of ≥1.0 g/dL) compared to 35.3% for iron sucrose (p=0.2254).

Non-dialysis-dependent chronic kidney disease

Study 1VIT04004 was an open-label, randomised active-control study, evaluating the safety and efficacy of Ferinject (n=147) vs. oral iron (n=103). Subjects in the Ferinject group received 1,000 mg of iron at baseline and 500 mg of iron at days 14 and 28, if TSAT was <30% and serum ferritin was <500 ng/mL at the respective visit. Subjects in the oral iron arm received 65 mg iron TID as ferrous sulphate from baseline to day 56. Subjects were followed-up until day 56. The primary efficacy endpoint was the percentage of subjects achieving an increase in Hb of ≥1.0 g/dL anytime between baseline and end of study or time of intervention. This was achieved by 60.54% of subjects receiving Ferinject vs. 34.7% of subjects in the oral iron group (p<0.001). Mean haemoglobin change to day 56/end of study was 1.0 g/dL in the Ferinject group and 0.7 g/dL in the oral iron group (p=0.034, 95% CI: 0.0, 0.7).

Gastroenterology

Inflammatory bowel disease
Study VIT-IV-CL-008 was a randomised, open-label study which compared the efficacy of Ferinject vs. oral ferrous sulphate in reducing ID anaemia in subjects with inflammatory bowel disease (IBD). Subjects received either Ferinject (n=111) in single doses of up to 1,000 mg iron once per week until the individually calculated iron dose (per Ganzoni formula) was reached (mean cumulative iron dose: 1,490 mg), or 100 mg iron BID as ferrous sulphate (n=49) for 12 weeks. Subjects receiving Ferinject showed a mean increase in Hb from baseline to Week 12 of 3.83 g/dL, which was non-inferior to 12 weeks of twice daily therapy with ferrous sulphate (3.75 g/dL, p=0.8016).
Study FER-IBD-07-COR was a randomised, open-label study comparing the efficacy of Ferinject vs. iron sucrose in subjects with remitting or mild IBD. Subjects receiving Ferinject were dosed according to a simplified dosing grid using baseline Hb and body weight (see section 4.2) in single doses up to 1,000 mg iron, whereas subjects receiving iron sucrose were dosed according to individually calculated iron doses using the Ganzoni formula in doses of 200 mg iron until the cumulative iron dose was reached. Subjects were followed-up for 12 weeks. 65.8% of subjects receiving Ferinject (n=240; mean cumulative iron dose: 1,414 mg) vs. 53.6% receiving iron sucrose (n=235; mean cumulative dose 1,207 mg; p=0.004) had responded at Week 12 (defined as Hb increase ≥2 g/dL). 83.8% of Ferinject-treated subjects vs. 75.9% of iron sucrose-treated subjects achieved a Hb increase ≥2 g/dL or had Hb within normal limits at Week 12 (p=0.019).

Women's health

Post partum
Study VIT-IV-CL-009 was a randomised open-label non-inferiority study comparing the efficacy of Ferinject (n=227) vs. ferrous sulphate (n=117) in women suffering from post-partum anaemia. Subjects received either Ferinject in single doses of up to 1,000 mg iron until their individually calculated cumulative iron dose (per Ganzoni formula) was reached, or 100 mg of iron as oral ferrous sulphate BID for 12 weeks. Subjects were followed-up for 12 weeks. The mean change in Hb from baseline to Week 12 was 3.37 g/dL in the Ferinject group (n=179; mean cumulative iron dose: 1,347 mg) vs. 3.29 g/dL in the ferrous sulphate group (n=89), showing non-inferiority between the treatments.

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.

Ferritin monitoring after replacement therapy
There is limited data from study VIT-IV-CL-008 which demonstrates that ferritin levels decrease rapidly 2-4 weeks following replacement and more slowly thereafter. The mean ferritin levels did not drop to levels where retreatment might be considered during the 12 weeks of study follow up. Thus, the available data does not clearly indicate an optimal time for ferritin retesting although assessing ferritin levels earlier than 4 weeks after replacement therapy appears premature. Thus, it is recommended that further re-assessment of ferritin should be made by the clinician based on the individual patient's condition.

5.2 Pharmacokinetic properties

Distribution
Positron emission tomography 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 1,000 mg of iron in ID subjects, maximum total serum iron levels of 37 µg/mL up to 333 µg/mL are obtained after 15 minutes to 1.21 hours respectively. 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 Preclinical safety data

Preclinical data revealed no special hazard for humans based on conventional studies of safety pharmacology, repeat dose toxicity and genotoxicity. Preclinical 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 in order to protect from light. 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

Ferinject is supplied in a vial (type I glass) with a stopper (bromobutyl rubber) and an aluminium cap as:
- 10 mL solution containing 500 mg iron. Available in pack sizes of 1 vial.

Not all pack sizes may be marketed.

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. MARKETING AUTHORISATION HOLDER

Zuellig Pharma Ltd.
Bangkok, Thailand

8. MARKETING AUTHORISATION NUMBER

1C 15022/63 (NC)

9. DATE OF REVISION OF THE TEXT

November 2020