Ferinject® (ferric carboxymaltose):
UAE, Oman, Bahrain, Kuwait & Qatar Abbreviated Prescribing Information

This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are requested to report any suspected adverse reactions.

Note: Before prescribing, please read the Summary of Product Characteristics (SmPC).

Pharmaceutical form: Iron as Ferric carboxymaltose as a solution for injection/infusion. **Indication Ferinject®** is indicated for the treatment of Iron deficiency in adult patients in whom oral iron therapy is not sufficiently effective, is ineffective or cannot be undertaken, such as cases where oral iron preparations cannot be tolerated or in the presence of inflammatory gastrointestinal diseases. **Ferinject®** should only be administered if the diagnosis of iron deficiency has been established and confirmed through appropriate laboratory investigations. **Dosage and Administration:** The individual amount of iron needed to replenish iron stores, by means of **Ferinject®** can be determined on the basis of the patient's body weight and haemoglobin (Hb) level. Iron requirements should be determined using the Ganzoni formula or the simplified dosing regimen. A single dose of **Ferinject®** should not exceed the following values: 15 mg iron/kg body weight (administered as an intravenous route injection) or 20 mg iron/kg body weight (administered as an intravenous infusion) or 1000 mg iron (20 ml **Ferinject®**). If the cumulative iron dose exceeds 20 mg iron/kg body weight or 1000 mg iron via **Ferinject®** the dose must be divided into two administrations with an interval of at least one week between them. Ganzoni formula: Total iron deficit [mg] = total cumulative dose [mg] = Body weight [kg] x (Target Hb - Actual Hb) [g/dL] x 2.4 + reserve iron [mg] **Ferinject®** must only be administered intravenously as an injection, or as an infusion, or as an undiluted as or directly into the venous line of the dialysis machine during haemodialysis. **Contraindications:** Hypersensitivity to the active substance or one of the excipients of the composition anaemia without confirmed iron deficiency; evidence of iron overload; first trimester of pregnancy. **Warnings and precautions:** The intravenous administration of parenteral iron products can cause immediate-type acute hypersensitivity reactions (anaphylactoid/ anaphylactic reactions), including anaphylactoid reactions which may be fatal. Such reactions have been reported even where previous administrations of parenteral iron products have been tolerated without complications. There are reports of hypersensitivity reactions that can progress to Kounis syndrome (acute allergic spasm of the coronary arteries that can result in myocardial infarction. **Ferinject®** should only be used if healthcare professionals who can assess and treat anaphylactic reactions are immediately available as well as only in an institution in which all facilities for resuscitation are available.B efore each administration of **Ferinject®**, patients should be actively questioned about previous adverse reactions to intravenous iron products. Patients should be carefully monitored for any signs and symptoms of a hypersensitivity reaction during and for at least 30 minutes after the administration of parenteral iron products Should allergic reactions or signs of intolerance occur during administration, the treatment must be stopped immediately. Parenteral iron can lead to hypophosphataemia which is transient and without clinical symptoms. 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 inflammatory bowel disease and osteoporosis) should be monitored for hypophosphataemic osteomalacia, secondary hyperparathyroidism, hereditary haemorrhagic telengectasia, should be monitored for hypophosphataemic osteomalacia, including serum phosphate control. In case of persistent hypophosphataemia, treatment with **Ferinject®** should be re-evaluated. Parenteral iron should only be administered to patients with hepatic dysfunction following a careful assessment of the risks and benefits. Parenteral iron administration should be avoided in patients with hepatic dysfunction due to iron overload, especially those with porphyria cutanea tarda, or any acute liver disease, Careful monitoring of the iron status is recommended to avoid iron overload. Parenteral iron should be administered with caution in cases of infections, asthma, eczema or atopic allergies. In the case of patients with bacteraemia, it is recommended to stop the administration of **Ferinject®**. **Interactions: Ferinject®** should not be administered concomitantly with oral iron preparations since the absorption of oral iron can be reduced. **Pregnancy and lactation:** There are limited clinical data from controlled studies on the use of **Ferinject®** in pregnant women. Foetal bradycardia may occur following the 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. **Effects on ability to drive and use machines:** No relevant studies have been performed. It is unlikely that **Ferinject®** has an effect on the ability to drive and use machines. **Undesirable effects:** The following undesirable effects were reported in clinical studies in which 9,456 adult patients and 82 children ≥ 1 year of age and adolescents received **Ferinject®** , as well as those reported from the post-marketing setting. Frequencies of undesirable effects: Not known: frequency cannot be estimated from the available data. The mostc ommonly reported adverse drug reactions (ADR) are nausea, injection/infusion site reactions, hypophosphataemia (based on laboratory findings), headache, facial flushing, dizziness and hypertension. Injection/ infusion site reactions include various ADRs, all of which are uncommon or rare. The most important serious adverse drug reactions associated with **Ferinject®** are uncommon hypersensitivity reactions. The most serious ADRs were anaphylactoid/anaphylactic reactions (rare); deaths were reported. In subjects who showed a decrease in serum phosphate during clinical trials, the lowest values were measured after about 2 weeks, and in most cases the values returned to baseline 12 weeks after treatmentw ith **Ferinject®**. For more information, see "Warnings and Precautions". *Hepatobiliary disorders* include Alanine aminotransferase (ALT) increased, aspartate aminotransferase (AST) increased, gamma glutamyltransferase (Y-GT) increased, lactate dehydrogenase (LDH) increased, alkaline phosphatase (ALP). *Immune system disordersUncommon (<1/100, ≥1/1000) side effects*include hypersensitivity reactions of immediate-type anaphylactic/anaphylactoid reactions which can potentially be lethal (see "Warnings and precautions"). (Please refer to the SmPC for a full array of symptoms). *General disorders and administration site symptoms* include (Pyrexia, fatigue, chest pain, oedema peripheral, chills, pain). *Nervous system disorders* (include Paraesthesia, taste disturbance (dysgeusia)), Cardiac disorders (include Tachycardia). *Vascular disorders* (include Hypotension). Rare (<1/1000, ≥1/10'000) sides effects include anxiety, loss of consciousness, syncope, presyncope, phlebitis, flatulence, Angioedema, dermatitis, pallor, distant skin discolouration and face oedema, dermatitis, malaise, influenza-like illness. **Overdose:** Accidentally exceeding the cumulative total dose, which is necessary for correcting the iron deficiency, can lead to an accumulation of iron in the iron stores and ultimately to haemosiderosis in these patients. This can be prevented by preventive control of the iron parameters serum ferritin and transferrin saturation. An unwanted accumulation of iron is to be treated according to standard medical practice.

Legal category: POM Date of Authorisation.
MA Holder: Vifor (International) Inc. Rechenstrasse 37, 9014 St.Gallen, Switzerland.
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Adverse events should be reported to Vifor International AG Rep office
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For any further information or inquiries please refer to full SMPC or please contact our local representative Vifor International AG Rep office: Aspin Tower · Aspin Commercial Building 33rd Floor, Office No: 3301
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