הודעה על החמרה (מידע בטיחות) בעלון לרופא

(מעודכן 02.2015)

תאריך אישור העלון : 02.2017

שם תכשיר באנגלית ומספר הרישום :

Ferinject- 146423333100, 146423333101

שם בעל הרישום _____כצט בע"מ_____

טופס זה מיועד לפרוט ההחמרות בלבד !

ההחמרות המבוקשות		
טקסט חדש	**טקסט נוכחי**	**פרק בעלון**
The use of FERINJECT is contraindicated in cases of: • Hypersensitivity to the active substance, to Ferinject or to any of its excipients listed in section 6.1 • Known serious hypersensitivity to other parentral iron products • anaemia not attributed to iron deficiency, e.g. other microcytic anaemia • evidence of iron overload or disturbances in utilisation of iro	The use of FERINJECT is contraindicated in cases of: • Hypersensitivity to ferric carboxymaltose complex, or to any of its excipients • anaemia not attributed to iron deficiency, e.g. other microcytic anaemia • evidence of iron overload or disturbances in utilisation of iron	**Contraindications**
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. 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	Parenterally administered iron preparations can cause hypersensitivity reactions including anaphylactoid reactions, which may be fatal (see section 5.3). Therefore, facilities for cardio-pulmonary resuscitation must be available. If allergic 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	**Special warnings and special precautions for use**

resuscitation facilities can be assured. Each patient should be observed for adverse effects for at least 30 minutes following each Ferinject injection. 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. *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, asthma, eczema or atopic allergies. 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 injection site may lead to irritation of the skin and potentially long lasting brown discolouration at the site of injection. In case of paravenous leakage, the administration of Ferinject must be stopped immediately.	ferric carboxymaltose. Each patient should be observed for adverse effects for at least 30 minutes following each FERINJECT injection. 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. Parenteral iron must be used with caution in case of acute or chronic infection, asthma, eczema or atopic allergies. 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. Caution should be exercised to avoid paravenous leakage when administering FERINJECT. Paravenous leakage of FERINJECT at the injection site may lead to brown discolouration and irritation of the skin. In case of paravenous leakage, the administration of FERINJECT must be stopped immediately.	

Excipients One millilitre 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.	One millilitre of undiluted FERINJECT contains up to 0.24 mmol (5.5 mg) of sodium. This has to be taken into account in patients on a sodium-controlled diet. The use of FERINJECT has not been studied in children.	
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 injection of Ferinject.	As with all parenteral iron preparations the absorption of oral iron is reduced when administered concomitantly.	**Interaction**
Pregnancy There are no adequate and well-controlled trials of Ferinject in pregnant women. 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. 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 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).	There are no or limited clinical data from the use of ferric carboxymaltose in pregnant women. A careful risk/benefit evaluation is required before use during pregnancy, especially during the first trimester. Preclinical data indicate that iron released from ferric carboxymaltose can cross the placenta in limited, controlled amounts. Treatment of pregnant animals with Ferinject at maternal non-toxic doses resulted in no adverse effects on embryos or foetuses. 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.	**Ferility, pregnancy and lactation**
Addition of: Phlebitis, presyncope[4] influenza like illness[4]		**Undesirable effects**

Pre-clinical 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.	Pre-clinical data revealed no special hazard for humans based on conventional studies of safety pharmacology, repeat dose toxicity and genotoxicity. Animal studies indicate that iron released from FERINJECT does cross the placental barrier and is excreted in milk. In reproductive toxicology studies using iron replete animals FERINJECT was associated with minor skeletal abnormalities in the fetus. 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	**Pre-clinical safety data**