הודעה על החמרה (מידע בטיחות) בעלון לרופא

תאריך 04.02.14

שם תכשיר באנגלית ומספר הרישום Ferrlecit 1256728020

שם בעל הרישום sanofi aventis Israel ltd

בטופס מוזכרים רק תתי הסעיפים שבהם נעשו שינויים במידע בטיחות, מידע מלא ניתן למצוא בעלון המלא.

טופס זה מיועד לפרוט ההחמרות בלבד!

ההחמרות המבוקשות		
טקסט חדש	**טקסט נוכחי**	**פרק בעלון**
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.		**Name of the medicinal product**
Ferrlecit is indicated in adults and children 6 years and above. //////////////////////////		**Therapeutic indications**
////////////////////////// Monitor carefully patients for signs and symptoms of hypersensitivity reactions during and following each administration of Ferrlecit. Ferrlecit 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 Ferrlecit injection (see section 4.4). *Pediatric population* Due to lack of clinical data on safety and efficacy, Ferrlecit solution for injection is not recommended in children younger than the age 6 years. //////////////////////		**Posology and method of administration**
Ferrlecit should not be used in - Hypersensitivity to the active substance, to Ferrlecit or any of its ~~one of the~~ excipients listed in section 6.1. - Known serious hypersensitivity to other parenteral iron products. - iron overload (haemochromatosis, chronic haemolysis) or iron utilisation disorders (sideroblastic anaemia, lead anaemia, thalassaemia), severe inflammatory diseases of the liver or kidneys,		**Contraindications**

~~- infants and small children under 3 years of age.~~ Due to the content of benzyl alcohol, Ferrlecit must not be given to premature babies or ~~newborns or premature~~ neonates. ~~Ferrlecit is not recommended for use in children between three and six years of age due to inadequate safety data.~~ Because of its sucrose content, this medicinal product must not be used in patients suffering from hereditary fructose intolerance, glucose-galactose malabsorption or saccharase-isomaltase deficiency.		
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, Crohn's disease). Ferrelcit 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. Each patient should be observed for adverse effects for at least 30 minutes following each Ferrlecit 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. ~~Ferrlecit should only be used with special caution in:~~ ~~patients with known allergic diathesis e.g. in asthmatics~~ ~~chronic inflammatory diseases (Crohn's disease, progressive rheumatoid arthritis)~~ //////////////////////////// Ferrlecit should not be used in patients suffering from the rare hereditary fructose intolerance.		**Special warnings and precautions for use**
//////////////////////////// Fertility Studies to assess the effect of Ferrlecit on fertility were not conducted.		**Pregnancy and lactation**