



אוגוסט, 2022

FERRLECIT, Solution for Injection/concentrate for solution for infusion

חומר פעיל:

Iron as sodium ferric gluconate complex 62.5 mg/5ml

ההתוויה המאושרת:

Ferrlecit is indicated in adults and children from 6 years and above. Severe iron deficiency states only when oral administration has been found impossible; in cases of gastrointestinal malabsorption which rules out oral iron therapy; patients treated by dialysis getting erythropoietin.

חברת סאנופי אוונטיס מבקשת להודיע על עדכון העלון לצרכן במתכונת עלון לרופא.

העדכונים העיקריים הינם:

4.3 Contraindications

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- premature babies, neonates, infants and small children ~~up to under~~ 6 years of age.

4.4 Special warnings and precautions for use

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Benzyl alcohol ~~contained in Ferrlecit~~ may cause toxic and anaphylactoid reactions in infants and children up to 3 years old.

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As benzyl alcohol may cross the placenta, solution for injection should **only** be used with caution in pregnancy (see also section 4.6).

4.6 Fertility, Pregnancy and lactation

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Foetal bradycardia may occur following administration of parenteral irons. It is usually transient and a consequence of a hypersensitivity reaction in the mother. ~~Foetal bradycardia may also be a consequence of severe adverse drug reactions in mothers including circulatory failure (severe hypotension, shock including in the context of anaphylactic reaction), especially during the second and third trimester.~~

4.8 Undesirable effects

Immune system disorders

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Rare: anaphylactic reactions including oedema ~~at in various sites in parts of~~ the body (~~angioedema~~), also in the ~~region-area~~ of the face, ~~oral cavity mouth~~ and ~~pharynx-throat~~ (e.g. ~~glottal oedema glottidis~~), ~~anaphylactoid reactions~~ and anaphylactic shock
Not known: hypersensitivity-like reactions (mostly fever and/or arthralgia and/or nausea/vomiting).



Cardiac disorders

Not known: Kounis syndrome, palpitations, tachycardia, foetal bradycardia ~~due to severe maternal hypotension or shock~~ (See section 4.6).

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Cardiac disorders

Palpitations, tachycardia

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Skin and subcutaneous tissue disorders

Facial erythema

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Vascular disorders

Hypertension, ~~facial reddening~~

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4.9 Overdose

Signs of an overdose with Ferlecit may be circulatory collapse, shock, pallor, dyspnoea, restlessness as well as ~~drowsiness~~ ~~confusion~~ and coma. Fever and convulsions have also been reported.

~~Excessive dosages~~ An overdose of Ferlecit ~~may~~ ~~can~~ lead to accumulation of iron in ~~storage sites~~ iron stores and potentially leading to haemosiderosis.

Treatment and appropriate supportive therapy must be given as soon as possible.

~~If serum~~ If iron overload is detected / confirmed by laboratory testing, a chelating agent such as deferoxamine may be considered. If blood iron levels exceed 3 mg/I-L and the iron binding capacity of transferrin is exceeded, i.v.-IV infusion of 1 to 2 g deferoxamine (maximum 16 mg/kg/hour) is recommended. ~~The~~ If necessary, the infusion should be repeated ~~on~~ the next day ~~if necessary~~ and the serum iron levels should be checked.

העלון המעודכן נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות וניתן לקבלו מודפס על ידי פנייה לבעל הרישום - סאנופי-אוונטיס ישראל בע"מ, רח' בני גאון 10 נתניה או בטלפון: 09-8633700.

להלן הקישור לאתר משרד הבריאות: <https://israeldrugs.health.gov.il/#!/byDrug>

בברכה,
ד"ר תמר גבע
רוקחת ממונה