



30.12.2020

רופא/ה רוקח/ת נכבד/ה,
ברצוננו להודיעך על עדכון בעלון לרופא

Ferrovin solution for injection

חומר פעיל :

Iron Sucrose 20 mg/ml

להלן עדכונים בעלון לרופא (טקסט מסומן ירוק משמעותו עדכון, טקסט מסומן צהוב משמעותו החמרה, טקסט משמעותו מחיקה):

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

FERROVIN is indicated for the **treatment** therapy of iron deficiency anaemia in the following **indications** cases:

- Where there is a clinical need for a rapid iron supply.
- In patients who cannot tolerate oral iron therapy or who are non-compliant.
- In active inflammatory bowel disease where oral iron preparations are ineffective.
- In chronic kidney disease when oral iron preparations are less effective.

The diagnosis of iron deficiency must be based on appropriate laboratory tests (e.g. Hb, serum ferritin, TSAT, serum iron, etc.).
(Hb haemoglobin, TSAT transferrin saturation)

Severe iron deficiency only when oral administration has been found impossible. In cases of gastro-intestinal malabsorption which rules out oral therapy, patients on dialysis treated with erythropoietin.

4.6 Fertility, pregnancy and lactation

Pregnancy

[....]

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.

[...]

4.8 Undesirable Effects

[...]



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Anaphylactoid/anaphylactic reactions were reported only in the post-marketing setting (estimated as rare). fatalities have been reported. See section 4.4

[...]

System Organ Class	Common (≥1/100, <1/10)	Uncommon (≥1/1,000, <1/100)	Rare (≥1/10,000, <1/1,000)	Frequency not known ¹⁾
Immune system disorders		Hypersensitivity		Anaphylactoid reactions, angioedema
Nervous system disorders	Dysgeusia	Headache, dizziness, paraesthesia, hypoaesthesia	Syncope, somnolence,	Depressed level of consciousness, confusional state, loss of consciousness, anxiety, tremor
Cardiac disorders			Palpitations	Bradycardia, tachycardia
Vascular disorders	Hypotension, hypertension	Flushing, Phlebitis		Circulatory collapse, thrombophlebitis
Respiratory, thoracic and mediastinal disorders		edema, dyspnoea		Bronchospasm
Renal and urinary disorders			Chromaturia	
Gastrointestinal disorders	Nausea	Vomiting, abdominal pain, diarrhoea, constipation		
Skin and subcutaneous tissue disorders		Pruritus, rash		Urticaria, erythema
Musculoskeletal and connective tissue disorders		Muscle spasms, cramps, myalgia, arthralgia, pain in extremity, back pain		
General disorders and administration site conditions	Injection /infusion site reaction ⁽²⁾	Chills, asthenia, fatigue, oedema peripheral, pain	chest pain, hyperdrosis, pyrexia,	cold sweat, malaise, pallor, influenza like illness ³⁾
Investigations		Alanine aminotransferase increased, aspartate aminotransferase increased, Gamma glutamyltransferase increased, Serum ferritin increased	blood lactate dehydrogenase increased	

¹⁾ Spontaneous reports from the post-marketing setting; estimated as rare

²⁾ The most frequently reported are: injection/infusion site pain, -extravasation, -irritation, -reaction, -discolouration, - haematoma, -pruritus.



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³⁾ Onset may vary from a few hours to several days.

Reporting of suspected adverse reactions:

[...]

<http://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>

[...]

6.4 Special precautions for storage

Prescribed storage conditions: **4 -25 °C**. ~~Store in the original package. Do not store at temperatures above 25°C. Do not freeze.~~ **Store in the original package in order to protect from light.**

[...]

העלון לרופא נשלח למאגר התרופות שבאתר משרד הבריאות www.health.gov.il לצורך העלאתו לאתר וניתן לקבלם מודפסים על ידי פניה לבעל הרישום LAPIDOT MEDICAL IMPORT AND MARKETING LTD Ltd, רח' השיטה 8, פארק התעשייה קיסריה 3088900 ישראל.

בברכה
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