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רופא/ה, רוקח/ת נכבד/ה,

הנדון: **עדכון עלון לרופא של פרינג'קט Solution for injection/ infusion**

אנו מבקשים להודיעכם כי העלון לרופא של התכשיר שבנדון עודכן. עדכון העלון כולל החמרות.

ההתוויה המאושרת:

Ferinject is indicated for treatment of iron deficiency when oral iron preparations are ineffective or cannot be used.
The diagnosis must be based on laboratory tests.

הרכב וחוזק חומר פעיל:

FERRIC CARBOXYMALTOSE 1800 MG/VIAL

בפירוט שלהלן מובא המידע בו בוצעו שינויים מהותיים בלבד.
תוספת טקסט או טקסט בעל שינוי משמעותי מסומן בצבע. מחיקת טקסט מסומנת בקו חוצה.

העדכונים בעלון לרופא נעשו בסעיפים הבאים:

Determination of the iron need
~~*For overweight patients, a normal body weight/blood volume relationship should be assumed when determining the iron requirement.*~~
~~*Post repletion, regular assessments should be completed to ensure that iron levels are corrected and maintained.*~~

Method of administration
Ferinject must only be administered by the intravenous route:

- by injection, or
- by infusion, or
- during a haemodialysis session undiluted directly into the venous limb of the dialyser.

Ferinject must not be administered by the subcutaneous or intramuscular route.

4.8 Undesirable effects
The most commonly reported ADR is nausea (occurring in 2.9% of the subjects), followed by injection/infusion site reactions, hypophosphatemia, headache, flushing, dizziness and hypertension.

System Organ Class	Common (≥1/100 to <1/10)	Uncommon (≥1/1000 to <1/100)	Rare (≥1/10000 to <1/1000)
Musculoskeletal and connective tissue disorders		Myalgia, back pain, arthralgia, pain in extremity, muscle spasms	

Injection/infusion site reactions[4] Includes the following preferred terms: injection/infusion site ~~burning~~, -pain, ~~bruising~~ -haematoma -discolouration, -extravasation, -irritation, -reaction, (all individual ADRs determined to be uncommon) and -paraesthesia (individual ADR determined to be rare)

5. Pharmacological Properties

Cardiology

Chronic heart failure

Study CONFIRM-HF was a double-blind, randomised, 2-arm study comparing Ferinject (n=150) vs. placebo (n=151) in subjects with chronic heart failure (CHF) and ID for a treatment period of 52 weeks. At Day 1 and Week 6 (correction phase), subjects received either Ferinject according to a simplified dosing grid using baseline Hb and body weight at screening (see section 4.2), placebo or no dose. At Weeks 12, 24 and 36 (maintenance phase) subjects received Ferinject (500 mg iron) or placebo if serum ferritin was <100 ng/mL or 100-299 ng/mL with TSAT < 20%, or no dose. The treatment benefit of Ferinject vs. placebo was demonstrated with the primary efficacy endpoint, the change in the 6-minute walk test (6MWT) from baseline to Week 24 (p=0.002). This effect was sustained throughout the study to Week 52 (p<0.001).

Pregnancy

Intravenous iron medicines should not be used during pregnancy unless necessary. 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, see section 4.6.

Limited safety data in pregnant women are available from study FER-ASAP-2009-01, a randomised, open-label study comparing Ferinject (n=121) vs. oral ferrous sulphate (n=115) in pregnant women in the second and third trimester with ID anaemia for a treatment period of 12 weeks. Subjects received Ferinject in cumulative doses of 1,000 mg or 1,500 mg of iron (mean cumulative dose: 1,029 mg iron) based on Hb and body weight at screening or 100 mg of oral iron BID for 12 weeks. The incidence of treatment-related adverse events was similar between Ferinject treated women and those treated with oral iron (11.4% Ferinject group; 15.3% oral iron group). The most commonly reported treatment-related adverse events were nausea, upper abdominal pain and headache. Newborn Apgar scores as well as newborn iron parameters were similar between treatment groups.

Special precautions for storage

Store in the original package in order to protect from light. Do not store above 30 °C. Do not ~~refrigerate or~~ freeze.

MANUFACTURER

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העלונים המעודכנים נשלחו לפרסום במאגר התרופות שבאתר משרד הבריאות http://www.health.gov.il.
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