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רופא/ה, רוקח/ת נכבד/ה,

הנדון: **<u>עדכון עלון לרופא של התכשיר</u>**

<u>VENOFER solution for injection</u>

נבקש לעדכנכם כי העלון לרופא של התכשיר שבנדון עודכן.

<u>התוויה מאושרת:</u>

Venofer is indicated for the treatment of iron deficiency in the following indications:

- 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)

<u>הרכב וחוזק חומר פעיל:</u>

One millilitre of solution contains 20 mg of iron as iron sucrose (iron(III)-hydroxide sucrose complex).

Each 5 ml ampoule of Venofer contains 100 mg iron as iron sucrose (iron(III)-hydroxide sucrose complex).

העדכון כולל החמרות.

בפירוט שלהלן מוצגים ה<u>שינויים המהותיים בלבד</u>.

- תוספת טקסט או עדכון משמעותי (החמרה) סומנו בצבע. מחיקת טקסט משמעותי סומנה בקו חוצה.

4.6 Fertility, pregnancy and lactation

<u>Pregnancy</u>

There is no data from the use of iron sucrose in pregnant women in the first trimester. Data (303 pregnancy

outcomes) from the use of Venofer in pregnant women in the second and third trimester showed no safety concerns for the mother or newborn.

A careful risk/benefit evaluation is required before use during pregnancy and Venofer should not be used during pregnancy unless clearly necessary (see section 4.4).

Iron deficiency anaemia occurring in the first trimester of pregnancy can in many cases be treated with oral iron. Treatment with Venofer should be confined to second and third trimester if the benefit is judged to outweigh the potential risk for both the mother and the fetus.

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.

Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity (see section 5.3).

4.8 Undesirable effects

General disorders and administration site conditions:

Frequency not known[1):]
influenza like illness[3)]

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

העלון המעודכן נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות http://www.health.gov.il.

כמו כן, ניתן לקבלם מודפסים על ידי פניה לחברת כצט בע"מ, רח' החרש 4 הוד השרון, 1-700-500-220.

בברכה,

רותם לונדון
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