5-Dec.-2013

Pharmacosmos A/S-Cigalah

Direct Health Professional Communication

Important information regarding CosmoFer®

Dear Health Care Professional

This letter is to inform you about information regarding indications, administration of CosmoFer® (low molecular weight iron dextran)

Summary of therapeutic indications (for adults only)

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

- When oral iron preparations cannot be used, e.g. due to intolerance, or in case of demonstrated lack of effect of oral iron therapy
- Where there is a clinical need to deliver iron rapidly to iron stores.

The diagnosis of iron deficiency must be based on appropriate laboratory tests (e.g. serum ferritin, serum iron, transferrin saturation and hypochromic red cells).

CosmoFer® should not be used for children. There is no documentation for efficacy and safety.

Further information on the safety concern**Test dose**: (all routes of administration)

Before administering the first dose to a new patient, a test dose of CosmoFer® corresponding to 25 mg iron or equal to 0.5 ml solution must be administered. If no adverse reactions are seen after 60 minutes, the remaining dose can be given.

Observation during administration

Patients should be observed carefully during the infusion. Anaphylactoid reactions to CosmoFer® are usually evident within a few minutes, and close observation is necessary to ensure recognition. If at any time during the intravenous administration of CosmoFer®, any signs of a hypersensitivity reaction or intolerance are detected, administration must be stopped immediately.

Resuscitative medication and personnel trained to evaluate and treat anaphylaxis should be available whenever a dose of iron dextran is administered.

P.O. BOX	19435	صنـدوق بريـــد
JEDDAH 21435 - SAUDI ARABIA		جـــدة
C.R.	4030034129	س.ت
C.C.	25967	رقم العضوية
TEL :	02 6136900	تليفون :
	02 6136905	
	02 6136907	
FAX :	02 6217253	فاكس :

Dosing/

Dosage/Calculation of total iron need:

a) Iron replacement in patients with iron deficiency anaemia:

The required dose has to be individually adapted according to the total iron deficit calculated by the following formula – haemoglobin in g/l mmol/l.

Total dose (mg Fe) – Hb in g/l:

(Body weight (kg) x (target Hb - actual Hb) (g/l) x 0.24) + mg iron for iron stores

Total dose (mg Fe) – Hb in mmol/l:

Body weight in kg x (target Hb in mmol/l – actual Hb in mmol/l) x 3.84 + mg iron for iron stores

For a body weight exceeding 35 kg :target haemoglobin = 150 g/l or 9.3 mmol/l and iron stores = 500 mg
For further information please refer to the product summary product characteristic (SPC).

b) Iron replacement for blood loss:

Iron therapy in patients with blood loss should be directed toward replacement of an amount of iron equivalent to the amount of iron represented in the blood loss. The formula above described is not applicable for simple iron replacement values. Quantitative estimates of the individual's periodic blood loss and hematocrit during the bleeding episode provide a convenient method of calculation of the required iron dose.

For further information please refer to the product summary product characteristic (SPC).

Dosage/Calculation of maximal dose per injection/infusion:

The normal recommended dosage schedule is 100-200 mg iron corresponding to 2-4 ml, two or three times a week depending on the haemoglobin level. However, if clinical circumstances require rapid delivery of iron to the body iron stores CosmoFer® may be administered as a total dose infusion up to a total replacement dose corresponding to 20 mg iron/kg body weight.

If the total necessary dose exceeds the maximum allowed daily dose, the administration has to be split

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Administration

CosmoFer® solution for infusion and injection can be administered by various different methods:

A. Intravenous injection: CosmoFer® may be administered in a dose of 100 – 200 mg iron (2-4 ml) by slow intravenous injection (0.2 ml/min) preferably diluted in 10 – 20 ml 0.9% sodium chloride or

5% glucose solution. On each occasion before administering a slow intravenous injection, 25 mg of iron should be injected slowly over a period of 1 to 2 minutes. If no adverse reactions occur within 15 minutes, the remaining portion of the injection may be given.

B. Intravenous infusion:CosmoFer® must be diluted only in 0.9% sodium chloride solution (normal saline) or in 5% glucose solution. CosmoFer® in a dose of 100-200 mg iron (2-4ml) may be diluted in 100 ml. On each occasion the first 25 mg of iron should be infused over a period of 15 minutes. If no adverse reactions occur during this time the remaining portion of the infusion should be given at an infusion rate of not more than 100 ml in 30 minutes.

Total dose infusion:
Immediately before administration the total amount of CosmoFer® required, determined from the dosage table or by calculation, is added aseptically to the required volume, usually 500 ml of sterile normal sodium chloride or 5% glucose solutions. The total amount of CosmoFer®, up to 20 mg/kg bodyweight, is infused intravenously over 4 – 6 hours. The first 25 mg of iron should be infused over a period of 15 minutes. The patient must be kept under close medical observation during this period. If no adverse reactions occur during this time, then the remainingportion of the infusion should be given. The rate of infusion may be increased progressively to 45 – 60 drops per minute. Patients should be observed carefully during the infusion and for at least 1 hour after completion

Total Dose Infusion (TDI) has been associated with an increased incidence of adverse reactions, in particular delayed hypersensitivity–like reactions. The intravenous administration of CosmoFer® by the total dose infusion method should be restricted to hospital use only.

C. Injection into dialyser: CosmoFer® may be administered during a haemodialysis session directly into the venous limb of the dialyser under the same procedures as outlined for intravenous infusion

D. Intramuscular injection: It is administered as a series of undiluted injections of up to 100 mg iron ml) each determined by the by the patient's body weight. If the patient is moderately active, injections may be given daily into alternate buttocks. In inactive or bedridden patients, the frequency of injections should be reduced to once or twice weekly.

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Contraindications

-Non-iron deficiency anaemia (e.g. haemolytic anaemia).
-Iron overload or disturbances in utilisation of iron (e.g. haemochromatosis, haemosiderosis).
-Patients with a history of asthma, allergic eczema or other atopic allergy should not be treated by intravenous injection.
-Drug hypersensitivity including iron mono- or disaccharide complexes and dextran.
-Decompensated liver cirrhosis and hepatitis.
-Acute or chronic infection, because parenteral iron administration may exacerbate bacterial or viral infections.
-Rheumatoid arthritis with symptoms or signs of active inflammation.
-Acute renal failure.

Special warning and precautions for use

The use of CosmoFer®, as with the parenteral use of other iron-carbohydrate complexes, carries a risk of immediate severe and potentially lethal anaphylactoid reactions. Patients should be closely observed during and immediately after administration.
-The risk is enhanced for patients with known (medical) allergy to pharmaceutical drugs.
-CosmoFer® may only be administered when facilities and equipment for handling acute anaphylactic reactions are available, including an injectable 1:1000 adrenaline solution. Additional treatment with antihistamines and/or corticosteroids should be given as appropriate.
-There is particularly increased risk of allergic reactions in patients with immune or inflammatory conditions (e.g. systemic lupus erythematosus, rheumathoid arthritis).
-When parenteral iron therapy is considered essential in patients with asthma, allergic disorders and inflammatory disorders, the intramuscular route is to be preferred.
-Hypotensive episodes may occur if intravenous injection is administered too rapidly.

Pregnancy and lactation:

CosmoFer® should not be used during the first trimester of pregnancy. If the benefit of CosmoFer®-treatment is judged to outweigh the potential risk to the foetus, it is recommended that treatment, should be confined to the second and third trimester, if treatment is clearly necessary.

It is unknown whether the complex iron-dextran is excreted in human or animal breast milk. It is preferable to not use CosmoFer® during breast-feeding

Further information

Further information can be found in summary of product characteristics.

The information provided in this letter has been reviewed by Saudi Food and Drug Authority.

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Call for reporting

Any suspected adverse reactions should be reported immediately to Cigalah Group on e-mail at drug-safety@cigalah.com.sa or fax: 12-6578861, or to Saudi Food and Drug Authority- National Pharmacovigilance and Drug Safety Center at fax: +966-11-2057662 or by e. mail to: npc.drug@sfda.gov.sa

Yours Sincerely

Ph. Ibrahim Hamidaddin
QA and Safety Manager
Cigalah Healthcare Sector

مؤسسات سقالة
Quality Assurance
Cigalah Group

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