Sufer®

Fe

IRON (III) HYDROXIDE SUCROSE COMPLEX
no dextran

IRON-CONTAINING INTRAVENOUS MEDICATION
for rapid clinical and hemorrhagic correction of Iron deficiency

Twice as rapid in action

than other forms of iron-containing medications

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Holder of gold medal International award "ISLQ International star for Leadership in Quality" in Paris

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SUMMARY OF PRODUCT CHARACTERISTICS SUFER®

COMPOSITION: active agent: 1 ml contains 20 mg of iron as iron (III) hydroxide sucrose;

excipient: water for injection.

DOSAGE FORM. Solution for intravenous injections.

PHARMACOTHERAPEUTIC GROUP. Antanemics for parenteral administration. Iron preparations. ATC code. B03A C02.

INDICATIONS. Iron deficiency: - if rapid replenishment of iron is necessary; - for patients who cannot tolerate or do not follow regular use of oral iron preparations; - in case of active inflammatory disease of digestive tract when oral iron preparations are ineffective.

INTRAVENOUS BOLUS ADMINISTRATION. Sufer® can also be administered slowly intravenously as an undiluted solution at a rate of 1 ml per minute (5 ml of Sufer (100 mg of iron) is administered in 5 min), but the maximum volume of the solution should not exceed 10 ml of Sufer (200 mg of iron) per injection. Before starting the infusion, a test dose is necessary: adults and children weighing more than 14 kg - 1 ml (20 mg of iron), and children weighing less than 14 kg - half the daily dose (1.5 mg of iron/kg) slowly for 1-2 minutes. If during the observation period, which lasts at least 15 minutes, there were no side effects, the remaining can be administered. Sufer® can be administered directly into the area of venous dialysis system strictly following the rules described for intravenous injection.

DOSE CALCULATION. The dose is calculated individually according to total iron deficiency of patient body by the formula: total iron deficit (mg) = body weight (kg) x (normal Hb (g/l) - patient Hb (g/l)) x 0.24* + deposited iron (mg). For patients weighing less than 35 kg: normal Hb - 130 g/l, deposited iron - 15 mg/kg body weight. For patients weighing more than 35 kg: normal Hb - 150 g/l, deposited iron - 500 mg. Ratio 0.24 = 0.0034 x 0.07 x 1000 (iron content in Hb = 0.34%, blood volume = 7% of body weight, rate 1000 = transfer of "g" in "mg").

CALCULATION OF DOSE TO REPLENISH IRON AFTER BLOOD LOSS OR DONATION. Dose of Sufer® necessary to compensate iron deficit is determined by the following formula: - in case of known amount of blood lost: intravenous administration of 200 mg of iron (= 10 ml of Sufer®) leads to the same increase in the concentration of Hb as transfusion of 1 unit of blood (= 400 ml with Hb concentration 150 g/l); Amount of iron, which must be compensated (mg) = amount of units of blood lost x 200, or required amount of Sufer® (ml) = number of units of lost blood x 10. - In case of reduced Hb: use the previous formula, but it should be noted that the depot iron does not need to be replenished. Amount of iron, which must be compensated (mg) = body weight (kg) x 0.24 x (normal Hb (g/l) - patient Hb) (g/l). For example: weight - 60 kg, Hb deficit = 10 g/l required amount of iron = 150 mg required amount of Sufer® = 7.5 ml. *Standard dosage.* Adults and elderly patients: 5-10 ml of Sufer® (100-200 mg of iron) 1-3 times a week depending on the Hb level. *Children:* there are only limited data on the use of drug by children. In case of clinical necessity (for quick replenishment of body with iron) administration of not more than 0.15 ml of Sufer® (3 mg of elemental iron) per 1 kg of body weight is recommended 1-3 times a week depending on the hemoglobin level.

MAXIMUM SINGLE DOSE: *Adults and elderly patients:* for injections: 10 ml of Sufer® (200 mg of iron), duration of administration not less than 10 minutes, no more than 3 times a week. for infusions: depending on indications, a single dose can reach 500 mg of iron. The maximum tolerated single dose is 7 mg of iron per 1 kg of body weight and is administered once per week, but it should not exceed 25 ml of Sufer® (500 mg of iron). Time of administration and method of dilution are specified above.

USE DURING PREGNANCY OR BREAST-FEEDING. There are limited data on the use of the drug by pregnant women that showed no undesirable effects of iron hydroxide sucrose on the run of pregnancy and health of fetus/child. There have not been conducted well-controlled studies in pregnant women so far. The results of research of the use of therapeutic doses in animals showed no direct or indirect harmful effects on pregnancy, development of embryo/fetus, delivery or postnatal development. However, risk/benefit ratio before using the drug in the second and third trimesters of pregnancy should be assessed. The drug is contraindicated for use in the first trimester of pregnancy. Penetration of gratuitous iron sucrose in mother's milk is unlikely. However, risk/benefit ratio before using the drug during the period of lactation should be assessed.

CHILDREN. There are only limited data on the use of the drug by children (see Dosage and Administration section). Appointment of the drug to children is recommended only for health reasons (to quickly replenish body with iron).

ADMINISTRATION DETAILS. Sufer® can be applied only in patients diagnosed with anemia under confirmed results of relevant studies (e.g., by the results of determination of serum ferritin, or hemoglobin (Hb), or hematocrit (Ht), or red blood cells count, or determination of their parameters - mean corpuscular volume, medium Hb content in erythrocyte or mean Hb concentration in erythrocyte). Before the use, inspect ampoules for the presence of precipitate and damage. Only brown water solution containing no precipitate can be applied.

Sufer® should be administered immediately after opening the ampoule. Intravenous iron preparations can cause potentially life-threatening allergic or anaphylactoid reactions. Therefore antiallergic treatment should be carried out in a room with appropriate equipment for cardio-pulmonary resuscitation. Due to the high risk of allergic reactions in patients with asthma, eczema, polyvalent allergy, allergic reactions to other parenteral iron preparations, the drug should be appointed with caution. Sufer® should be applied with extreme caution in patients with liver disorders, including those caused by increased ferritin, and in patients with acute or chronic infection.

Parenteral administration of iron can negatively affect the run of bacterial or viral infection. Also, caution is required when the drug is administered to people with low serum ability to bind iron and/or folic acid deficiency. Results of studies in patients with hypersensitivity reactions to iron dextran showed no complications during treatment with Sufer®. The rate of drug administration should be strictly adhered to prevent the development of arterial hypotension. High incidence of undesirable side effects (especially the emergence of hypotension) is associated with dose increase or increased rate of administration. Extravascular leakages should be avoided, as it leads to pain, inflammation, tissue necrosis and skin discoloration to brown.

Ability to affect the reaction speed when driving a car or operating other machinery. Unlikely. But in case of adverse reactions such as dizziness, confusion, you should refrain from driving or operating other machines until symptoms disappear.

Interaction with other medicinal products and other forms of interaction. Sufer® should not be used concurrently with oral iron-containing drugs, because thus the absorption of internally used iron is reduced. Therefore, treatment with oral iron preparations should begin no earlier than 5 days after the last injection of Sufer®.

PRESCRIPTION CATEGORY. On prescription.

Information for the professional activity of medical and pharmaceutical staff

1.SUMMARY OF PRODUCT CHARACTERISTICS SUFER®

2. Al-Momen A.K., Al-Meshari A.,Al-Nuaim L., Saddique A., Abotabib Z., Khashogji T., Abbas M. Intravenous iron sacrose complex in the treatment of iron deŽciency anemia during pregnancy// Eur.J. of Obstetr. and Gynecol. and Repr.Biol.- 1996.-Vol. 69.-P.121-124.

3. Al-Momen., Huraib S.O., Mitwalli A.H., Al-Wakeel J., Abu-Aisha H., Saddigue A. Enhancement of RhEpo e'ect by iron (III)-hydroxide sucrose complex in haemodialysis patients// 1999.- Febr

200 mg #1 concentrate for preparation of infusion solution with a solvent in a complete set

A **25** % decrease

in required erythropoetin when used in combined modality therapy.

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