

Feofer®

Iron Sucrose Injection USP

QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ampoule contains 5 mL Iron Sucrose USP equivalent to elemental Iron (Iron III) 100 mg (20 mg/mL).

PHARMACEUTICAL FORM AND PRESENTATION

Solution for injection or concentrate of solution for infusion.

Feofer® is a dark brown, non transparent, sterile aqueous solution of iron sucrose in water for injections.

INDICATIONS

Feofer® is indicated for the treatment of iron deficiency in the following conditions:

- 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
- Adults and pediatric patients above 2 years and older with Chronic Kidney Diseases (CKD)

Feofer® should only be administered where the indication is confirmed by appropriate investigations (e.g. Haemoglobin (Hb), serum ferritin, serum iron).

DOSAGE AND ADMINISTRATION

Administration

Feofer® must only be administered by the intravenous route. This may be by a slow intravenous injection or by an intravenous drip infusion.

Feofer® MUST NOT BE USED FOR INTRAMUSCULAR (IM) INJECTION .

Intravenous drip infusion:

Feofer® must be diluted only in sterile 0.9% w/v sodium chloride solution:

- 100 mg iron (5 mL Feofer®) in maximum 100 mL sterile 0.9% w/v sodium chloride solution
- 500 mg iron (25 mL Feofer®) in maximum 500 mL sterile 0.9% w/v sodium chloride solution

For stability reasons, dilutions to lower Feofer® concentrations are not permissible.

As infusion, maximum tolerated single dose per day given is not more than once per week:

- Patients above 70 kg: 500 mg iron (25 mL Feofer®) in at least 3 ½ hours
- Patients of 70 kg and below: 7 mg iron / kg body weight in at least 3 ½ hours

Dilution must take place immediately prior to infusion, the solution should be administered as follows:

- 100 mg iron (5 mL Feofer®) in at least 15 minutes
- 200 mg iron (10 mL Feofer®) in at least 30 minutes
- 300 mg iron (15 mL Feofer®) in at least 1 ½ hours
- 400 mg iron (20 mL Feofer®) in at least 2 ½ hours

Intravenous injection:

Feofer® can be administered undiluted by slow intravenous injection as follows:

- 100 mg iron (5 mL Feofer®) in at least 5 minutes
- 200 mg iron (10 mL Feofer®) in at least 10 minutes.

Injection into dialyser:

Feofer® may be administered during a haemodialysis session directly into the venous limb of the dialyser under the same conditions as for intravenous injection.

DOSAGE

Calculation of dosage:

The total cumulative dose of Feofer®, equivalent to the total iron deficit (mg), is determined by the haemoglobin (Hb) level and body weight. The dose of Feofer® must be individually determined for each patient according to the total iron deficit calculated with the following formula:

$$\text{Total iron deficit [mg]} = \text{body weight [kg]} \times (\text{target Hb} - \text{actual Hb}) [\text{g/dl}] \times 2.4^* + \text{depot iron [mg]}$$

Below 35 kg body weight: Target Hb = 13 g/dl and depot iron = 15 mg/kg body weight

35 kg body weight and above: Target Hb = 15 g/dl and depot iron = 500 mg

* Factor 2.4= 0.0034 x 0.07 x 1000: Iron content of haemoglobin ≈ 0.34%
Blood volume ≈ 7% of body weight
Conversion from g/dl to mg/l = Factor 1000

$$\text{Total amount of Feofer® to be administered (in mL)} = \frac{\text{Total iron deficit [mg]}}{20\text{mg/mL}}$$

The table below indicates the total number of ampoules of Feofer® to be administered (1 ampoule of Feofer® corresponds to 5 mL).

Body Weight (kg)	Total number of Feofer® ampoules to be administered (1 ampoule of Feofer® corresponds to 5 mL)			
	Hb 6 g/dl	Hb 7.5 g/dl	Hb 9 g/dl	Hb 10.5 g/dl
5	1.5	1.5	1.5	1
10	3	3	2.5	2
15	5	4.5	3.5	3
20	6.5	5.5	5	4
25	8	7	6	5.5
30	9.5	8.5	7.5	6.5
35	12.5	11.5	10	9
40	13.5	12	11	9.5
45	15	13	11.5	10
50	16	14	12	10.5
55	17	15	13	11
60	18	16	13.5	11.5
65	19	16.5	14.5	12
70	20	17.5	15	12.5
75	21	18.5	16	13
80	22.5	19.5	16.5	13.5
85	23.5	20.5	17	14
90	24.5	21.5	18	14.5

If the total necessary dose exceeds the maximum allowed single dose, then the administration has to be split.

NORMAL POSOLOGY:

Adults and the elderly:

5-10 mL Feofer® (100-200 mg iron) one to three times a week depending on the haemoglobin level.

Children:

There is limited data on children under study conditions. If there is a clinical need, it is recommended not to exceed 0.15 mL Feofer® (3 mg iron) per kg one to three times per week depending on the haemoglobin level.

Maximum tolerated single dose:

As injection, maximum tolerated dose per day, given not more than three times per week:

- 200 mg iron (10 mL Feofer®) injected over at least 10 minutes.

As infusion, maximum tolerated single dose per day given not more than once per week:

- Patients above 70 kg : 500 mg iron (25 mL Feofer®) in at least 3 ½ hours
 - Patients of 70 kg and below: 7 mg iron / kg body weight in at least 3 ½ hours
- The maximum tolerated single dose is 7 mg iron per kg body weight given once per week, but not exceeding 500 mg iron. For administration time and dilution ratio see 'Dosage and Administration' section. The infusion times given in the 'Dosage and Administration' section must be strictly adhered to, even if the patient does not receive the maximum tolerated single dose.

CONTRAINDICATIONS

The use of Iron Sucrose Injection is contra-indicated in cases of:

- Iron overload or disturbances in utilisation of iron.
- Known hypersensitivity to Iron Sucrose Injection or any of its inactive components.
- First trimester of pregnancy.

WARNINGS AND PRECAUTIONS

Parenterally administered iron preparations can cause allergic or anaphylactoid reactions, which can be potentially fatal. Therefore, antiallergic treatment should be in place with the established cardio-pulmonary resuscitation procedures.

In patients with a history of asthma, eczema, other atopic allergies or allergic reactions to other parenteral iron preparations, Iron Sucrose Injection should be administered with care as they are particularly at risk of an allergic reaction. However it was shown in a study with a limited number of iron dextran sensitive patients that Iron Sucrose Injection could be administered with no complications.

Iron Sucrose Injection should be administered with care in patients with liver dysfunction.

Iron Sucrose Injection must be used with care in patients with acute or chronic infection who have excessive ferritin values as parenterally administered iron can unfavourably influence a bacterial or viral infection.

Hypotensive episodes may occur if the injection is administered too rapidly.

Paravenous leakage must be avoided because leakage of Iron Sucrose Injection at the injection site may lead to pain, inflammation, tissue necrosis and brown discoloration of the skin.

PREGNANCY & LACTATION

Iron Sucrose has been assigned to pregnancy category B. Data on a limited number of exposed pregnancies indicated no adverse effects of Iron Sucrose Injection on pregnancy or on the health of the foetus/newborn child. No well-controlled studies in pregnant women are available to date. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/foetal development, parturition or postnatal development.

Nevertheless, risk/benefit evaluation is required.

Non metabolised Iron Sucrose Injection is unlikely to pass into the mother's milk. No well-controlled clinical studies are available to date. Animal studies do not indicate direct or indirect harmful effects to the nursing child.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

It is unlikely that Iron Sucrose Injection has an influence on the ability to drive and use machines.

ADVERSE EFFECTS

In particular metallic taste, headache, paraesthesia, hypotension, tachycardia, palpitations, bronchospasm, dyspnoea, nausea, vomiting, abdominal pain, diarrhoea, pruritus, urticaria, rash, muscle cramps, myalgia, fever, shivering, flushing, chest pain and tightness, injection site disorders such as burning and swelling may occur.

OVERDOSAGE

Overdosage can cause acute iron overloading which may manifest itself as haemosiderosis. Overdosage should be treated with supportive measures and, if required, with an iron chelating agent.

PHARMACEUTICAL PRECAUTIONS

Instructions for use / handling

Ampoules should be visually inspected for sediment and damage before use. Only those with a sediment free and homogenous solution must be used. See also shelf-life. The diluted solution must appear as brown and clear.

Feofer® must only be mixed with sterile 0.9% w/v Sodium Chloride solution. No other intravenous diluent solutions and therapeutic agent should be used as there is the potential for precipitation and/or interaction.

From a microbiological point of view, the product should be used immediately after dilution with sterile 0.9% sodium chloride.

Store in original carton. Do not store above 25 °C. Do not freeze. Keep away from light. Keep out of reach of children.

PACKAGING

Feofer® Injection: Box containing one ampoule which contains 5 mL Iron Sucrose USP equivalent to elemental Iron (Iron III) 100 mg (20 mg/mL).

Each box also contains,

- One bottle of 100 mL Sodium Chloride 0.9% Injection (Normal Saline)
- 5 mL Disposable Syringe
- Infusion set
- Plastic Hanger
- First Aid Band
- Alcohol Pad

SK•F

Manufactured by
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