Bosch For Medical Professional Only

Merofer 100mg/5ml INJECTION

(I r o n S u c r o s e)

Ampoules Intravenous Iron Therapy

میروفر ۱۰۰ ملی گرام/۵ ملی لیٹر انجکشن

(آئرن سکروز)

DESCRIPTION:
Merofer (Iron Sucrose Injection) an iron replacement product, is a brown, sterile, aqueous, complex of polynuclear iron (III)-hydroxide in sucrose for intravenous use. Iron sucrose injection has a molecular weight of approximately 34,000 to 60,000 daltons and molecular formula $[Na_2Fe_5O_8(OH).3(H_2O)]n.m(C_{12}H_{22}O_{11})$ where n is the degree of iron polymerization and m is the number of sucrose molecules associated with the iron (III)-hydroxide.

COMPOSITION:
Each ampoule contains:
Elemental Iron (III).....100mg
as Iron Sucrose M.S.
(Product Specs.: U.S.P.)

The total osmolarity of the solution is 1150-1350 mOsmol/L.

PHARMACODYNAMIC PROPERTIES:
Pharmacotherapeutic group: Anti-anaemic preparation, iron, parenteral preparation, ATC code: B03AC

Mechanism of Action:
The polynuclear iron core has a structure similar to that of the core of the physiological iron storage protein ferritin. The complex is designed to provide, in a controlled manner, utilisable iron for the iron transport and storage proteins in the body. following intravenous administration, the polynuclear iron core from the complex is taken up predominantly by the reticuloendothelial system in the liver, spleen, and bone marrow. In a second step, the iron is used for the synthesis of Hb, myoglobin and other iron-containing enzymes, or stored primarily in the liver in the form of ferritin.

PHARMACOKINETIC PROPERTIES
Distribution:
Intravenous injection of a single 100 mg iron dose of iron sucrose, maximum total serum iron concentrations were attained 10 minutes after injection and had an average concentration of 538 µmol/l. The volume of distribution of the central compartment corresponded well to the volume of plasma (approximately 3 litres).

Metabolism:
Upon injection, sucrose largely dissociates and the polynuclear iron core is mainly taken up by the reticuloendothelial system of the liver, spleen, and bone marrow. At 4 weeks after administration, red cell iron utilization ranged from 59 to 97%.

Elimination:
The iron sucrose complex has a weight average molecular weight (Mw) of approximately 43 kDa, which is sufficiently large to prevent renal elimination. Renal elimination of iron, occurring in the first 4 hours after injection of a **Merofer** dose of 100 mg iron, corresponded to less than 5% of the dose. After 24 hours, the total serum iron concentration was reduced to the pre-dose level. Renal elimination of sucrose was about 75% of the administered dose.

THERAPEUTIC 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.

DOSAGE AND ADMINISTRATION:
The cumulative dose of **Merofer** must be calculated for each patient individually and must not be exceeded. If the total necessary dose exceeds the maximum allowed single dose, then the administration must be divided.

Adults:
Merofer (100 - 200 mg iron) i.e. 5 - 10 ml, 1 to 3 times a week.

Paediatrics:
The use of **Merofer** has not been adequately studied in children and, therefore, **Merofer** is not recommended for use in children.

Dosage calculation:
Total **Merofer** to be administered (in ml)= $\frac{\text{Total iron deficit [mg]}}{\text{20mg iron/ml}}$

Total amount of **Merofer** (ml) to be administered according to body weight, actual Hb level and target Hb level.

BW	Total amount of Merofer (20 mg iron per ml) to be administered			
	Hb 6.0 g/dl	Hb 7.5 g/dl	Hb 9.0 g/dl	Hb 10.5 g/dl
30 kg	47.5 ml	42.5 ml	37.5 ml	32.5 ml
35 kg	62.5 ml	57.5 ml	50 ml	45 ml
40 kg	67.5 ml	60 ml	55 ml	47.5 ml
45 kg	75 ml	65 ml	57.5 ml	50 ml
50 kg	80 ml	70 ml	60 ml	52.5 ml
55 kg	85 ml	75 ml	65 ml	55 ml
60 kg	90 ml	80 ml	67.5 ml	57.5 ml
65 kg	95 ml	82.5 ml	72.5 ml	60 ml
70 kg	100 ml	87.5 ml	75 ml	62.5 ml
75 kg	105 ml	92.5 ml	80 ml	65 ml
80 kg	112.5 ml	97.5 ml	82.5 ml	67.5 ml
85 kg	117.5 ml	102.5 ml	85 ml	70 ml
90 kg	122.5 ml	107.5 ml	90 ml	72.5 ml

METHOD OF ADMINISTRATION:
Merofer must only be administered by the intravenous route. This may be by a slow intravenous injection, by an intravenous drip infusion or directly into the venous line of the dialysis machine.

Intravenous drip infusion
When administered by intravenous infusion, the injection must be diluted with 0.9% m/V Sodium Chloride Injection to a concentration of 1.0-2.0 mg/mL of elemental iron. Dilution must take place immediately prior to infusion and the solution should be administered as follows:

Merofer dose (mg of iron)	Merofer dose (ml of Merofer)	Maximum dilution volume of sterile 0.9% m/V NaCl solution	Minimum Infusion Time
50 mg	2.5 ml	50 ml	8 minutes
100 mg	5 ml	100 ml	15 minutes
200 mg	10 ml	200 ml	30 minutes

Intravenous injection
Merofer may be administered by slow intravenous injection at a rate of 1 ml undiluted solution per minute and not exceeding 10 ml **Merofer** (200 mg iron) per injection.

Injection into venous line of dialysis machine
Merofer may be administered during a haemodialysis session directly into the venous line of the dialysis machine under the same conditions as for intravenous injection.

CONTRAINDICATIONS:
- Hypersensitivity to the active substance, to **Merofer** or any of its excipients
- Known serious hypersensitivity to other parenteral iron products
- Anaemia not caused by iron deficiency
- Evidence of iron overload or hereditary disturbances in utilisation of iron.

WARNINGS AND PRECAUTIONS:
Hypersensitivity Reactions
Serious hypersensitivity reactions, including anaphylactic-type reactions, some of which have been lifethreatening and fatal, have been reported in patients receiving **Merofer**. If hypersensitivity reactions or signs of intolerance occur during administration, stop **Merofer** immediately. Monitor patients for signs and symptoms of hypersensitivity during and after **Merofer** administration for at least 30 minutes and until clinically stable following completion of the infusion.

Hypotension
Merofer may cause clinically significant hypotension. Monitor for signs and symptoms of hypotension following each administration of **Merofer**. Hypotension following administration of **Merofer** may be related to the rate of administration and/or total dose administered.

Iron Overload
Excessive therapy with parenteral iron can lead to excess storage of iron with the possibility of iatrogenic hemosiderosis. All adult and pediatric patients receiving **Merofer** require periodic monitoring of hematologic and iron parameters. Transferrin saturation (TSAT) values increase rapidly after intravenous administration of iron sucrose. Do not perform serum iron measurements for at least 48 hours after intravenous dosing.

DRUG INTERACTIONS:
As with all parenteral iron preparations, **Merofer** should not be administered concomitantly with oral iron preparations since the absorption of oral iron is reduced. Therefore, oral iron therapy should be started at least 5 days after the last injection of **Merofer**.

ADVERSE EFFECTS:
Common:
Dysgeusia, Hypotension, hypertension, Nausea, Injection/infusion site reaction

Uncommon:
Hypersensitivity, Headache, dizziness, paraesthesia, hypoaesthesia, Flushing, phlebitis, Dyspnoea, Vomiting, abdominal pain, diarrhoea, constipation, Pruritus, rash, Muscle spasm, myalgia, arthralgia, pain in extremity, back pain, Chills, asthenia, fatigue, oedema peripheral, pain, Alanine aminotransferase increased, aspartate aminotransferase increased, gamma-glutamyltransferase increased, serum ferritin increased.

Rare:
Syncope, somnolence, Palpitations, Chromaturia, Chest pain, hyperdrosis, pyrexia, Blood lactate dehydrogenase increased.

Not Known:
Anaphylactoid / anaphylactic reactions, angioedema, Depressed level of consciousness, confusional state, loss of consciousness, anxiety, tremor, Bradycardia, tachycardia, Kounis syndrome, Circulatory collapse, thrombophlebitis, Bronchospasm, Urticaria, erythema, Cold sweat, malaise, pallor, influenza like illness.

USE IN PREGNANCY AND LACTATION:
Pregnancy:
Iron deficiency anaemia occurring in the first trimester of pregnancy can in many cases be treated with oral iron. Treatment with **Merofer** should be confined to second and third trimester if the benefit is judged to outweigh the potential risk for both the mother and the foetus. Foetal bradycardia may occur following administration of parenteral irons. The unborn baby should be carefully monitored during intravenous administration of parenteral irons to pregnant women. A careful risk/benefit evaluation is required before use during pregnancy and **Merofer** should not be used during pregnancy unless clearly necessary.

Lactation:
There is limited information on the excretion of iron in human milk following administration of intravenous iron sucrose, therefore the risk/benefit should be assessed. Non metabolised iron sucrose is unlikely to pass into the mother's milk.

OVERDOSE:
Overdose can cause iron overload which may manifest itself as haemosiderosis. Overdose should be treated, as deemed necessary by the treating physician, with an iron chelating agent or according to standard medical practice.

INCOMPATIBILITIES:
This medicinal product must not be mixed with other medicinal products except sterile 0.9% m/V sodium chloride solution for dilution. There is the potential for precipitation and/or interaction if mixed with other solutions or medicinal products.

SPECIAL PRECAUTIONS FOR DISPOSAL AND OTHER HANDLING:
Ampoules or vials should be visually inspected for sediment and damage before use. The diluted solution must appear as brown and clear.

SHELF LIFE:
3 years
The product should be used immediately after opening of the container or after dilution with sterile 0.9% m/V sodium chloride solution.

STORAGE AND INSTRUCTIONS:
Protect from heat & light, store below 25°C.
Do not freeze.
The expiration date refer to the product correctly stored at the required condition.
Store in original packing.
Do not use if Injection is leaking or solution contains foreign matter.
Keep out of the reach of children.
Patients and healthcare professionals can also report suspected adverse drug reaction at ade@bosch-pharma.com.
To be sold on prescription of a registered medical practitioner only.

PRESENTATION: Merofer Injection 100mg/5ml: Pack of 5's Ampoules

ہدایات:-

روشنی اور گرمی سے محفوظ ۲۵ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔
منجمد ہونے سے محفوظ رکھیں۔
دوا کو اسکی اصل پیکنگ میں رکھیں۔
انجکشن لیک ہونے یا اس میں کوئی غیر حل پذیر شے نظر آئے تو ہرگز استعمال نہ کریں۔
بچوں کی پہنچ سے دُور رکھیں۔
صرف مستند ڈاکٹر کے نسخے پر فروخت کے لئے۔

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