Data Sheet

FERRUM H INJECTION

Iron polymaltose compound

PRESENTATION

A slightly viscous, dark reddish brown liquid. Odour faintly malt-like. Each ampoule of FERRUM H contains the equivalent of 100 mg of iron.

USES

Actions

FERRUM H is complexed in an aqueous, approximately isotonic solution for intramuscular injection. The complex is stable over a wide pH range (1-14) and each ampoule contains the equivalent of 50 mg iron per mL. Pharmacological tests have shown that the complex has a low toxicity with a LD_{50} (intravenous) of 400 mg iron per kg in white mice.

Pharmacokinetics

After an infusion of 100 mg iron as FERRUM H in 48 mL 0.9% sodium chloride, at a rate of 1.7 mL/min, a C_{max} (in serum) of 25.1 mcg/mL iron was observed. The terminal half-life was 22.4 hours. The MRT 20.2 hours and the V_D (distribution volume) 2.93 litres. Renal elimination is less than 1% of the total dosage.

Iron polymaltose shows a high structural homogeneity and thus steady delivery of the complexed iron to endogenous iron binding proteins.

Taken up from plasma by the reticuloendothelial system (RES), the iron is split off, binds to transferrin and partially re-enters the plasma from where it reaches the bone marrow for haemoglobin synthesis.

Indications

For the prevention and treatment of iron deficiency anaemia in the following circumstances:

- When oral therapy is contraindicated
- When enteric absorption of iron is defective
- When patient non-compliance or persistent gastrointestinal intolerance makes oral therapy impractical
- Treating iron deficiency anaemia of prematurity and that occurring in geriatric patients
- Treating iron deficiency states discovered in the third trimester of pregnancy
- Anaemia resulting from excessive blood loss
- Where contact between the doctor and patient occurs at irregular intervals

DOSAGE AND ADMINISTRATION

Intramuscular Use

Technique of Injection

The technique of injection is of crucial importance. FERRUM H should never be injected into the arm or other exposed areas. The wrong method may result in pain and discolouration of the skin.

The following method of ventro-gluteal injection according to HOCHSTETTER is recommended instead of the normal method of injection in the top outer quadrant of the gluteus maximus muscle:

1. The length of the needle should be at least 5-6 cm. The lumen of the needle should not be too wide.
2. According to HOCHSTETTER, the site of injection is determined as follows: First point A is found, corresponding to the ventral iliac spine. If the patient lies on the right side, for instance, the middle finger of the left hand is placed on point A. The index finger is extended away from the middle finger, so that it comes to lie below the iliac crest, at point B. The triangle lying between the proximal phalanges of the middle and index fingers represents the site of injection. This is disinfected in the usual way.
3. Before the needle is inserted, the skin over the site of injection is pulled down, about 2 cm, to give an S-shaped puncture channel. This prevents the injected solution from running back into the subcutaneous tissues and discolouring the skin.
4. The needle is introduced more or less vertically to the skin surface, angled to point towards the iliac crest rather than the hip joint.
5. After the injection, the needle is slowly withdrawn and pressure from a finger applied beside the puncture site. This pressure is maintained for about one minute.
6. The patient should move about after the injection.

Calculation of Required Dose

The figures in the accompanying dosage table have been calculated using the following formula taken from GANZONI (Wchweiz. Med. Wschr. 100, 301-619, 1970):

$$\text{Weight (kg)} \times \underbrace{(\text{normal Hb} - \text{actual Hb in g/L}) \times 0.24}_{\text{Hb-iron deficiency}} + \text{iron depot}$$

Note: factor 0.24 = 0.0034 x 0.07 x 1000
(for the purposes of this calculation, iron content of the haemoglobin = 0.34%, blood volume = 7% of the body weight, 1000 is the conversion from grams to milligrams).

The above formula can also be used to calculate the total iron deficit.

Example of Calculation

Assuming patient weighing 60 kg, normal Hb 150g/L, actual Hb 60g/L then:

HB-iron deficiency = 60 x (150-60) x 0.24 = 1296 mg + 500 mg = 1800 mg iron

Therefore patient requires 1800 mg iron or 18 ampoules.

The requirements of iron reserves (stored iron) (ca. 15 mg per kg up to a weight of about 34 kg, total of 500 mg about 34 kg body weight).

	Body weight < 34 kg	**Body weight > 34 kg**
Normal Hb	130 g/L	150 g/L

Dosage Table

Dosage table for the determination of the total millilitres of FERRUM H injection required.

Body weight kg	**Hb 60 g/L**		**Hb 75 g/L**		**Hb 90 g/L**		**Hb 105 g/L**	
	mL	**ampoules**	**mL**	**ampoules**	**mL**	**ampoules**	**mL**	**ampoules**
5	3	1.5	3	1.5	3	1.5	2	1
10	6	3	6	3	5	2.5	4	2
15	10	5	9	4.5	7	3.5	6	3
20	13	6.5	11	5.5	10	5	8	4
25	16	8	14	7	12	6	11	5.5
30	19	9.5	17	8.5	15	7.5	13	6.5
35	25	12.5	23	11.5	20	10	18	9
40	27	13.5	24	12.	22	11	19	9.5
45	30	15	26	13	23	11.5	20	10
50	32	16	28	14	24	12	21	10.5
55	34	17	30	15	26	13	22	11
60	36	18	32	16	27	13.5	23	11.5
65	38	19	33	16.5	29	14.5	24	12
70	40	20	35	17.5	30	15	25	12.5
75	42	21	37	18.5	32	16	26	13
80	45	22.5	39	19.5	33	16.5	27	13.5
85	47	23.5	41	20.5	34	17	28	14
90	49	24.5	43	21.5	36	18	29	14.5

Administer 2 mL by intramuscular injection every second day until the total dose is attained or administer 4 mL at longer intervals. Regular determination of Hb level is recommended.

Maximum Single Daily Dose by Intramuscular Injection

Infants up to 5 kg body weight: 0.5 mL
Children of 5-10 kg body weight: 1 mL
Patients weighing > 10 kg to 45 kg: 2 mL
Adults: 4 mL

CONTRAINDICATIONS

FERRUM H should not be given to patients presenting with any of the following conditions:

- Hypersensitivity to iron(III) hydroxide polymaltose complex
- Anaemia not caused by simple iron deficiency (e.g. haemolytic anaemia, megablastic anaemia caused by Vitamin B_{12} deficiency, disturbances in erythropoesis, hypoplasia of the marrow)
- Iron overload (e.g. haemochromatosis, haemosiderosis)
- Ostler-Rendu-Weber syndrome
- Chronic polyarthritis
- Bronchial asthma
- Infectious renal complaints in acute phase
- Uncontrolled hyperparathyroidism
- Decompensated hepatic cirrhosis
- Infectious hepatitis
- During the first trimester of pregnancy

As elemental iron tends to accumulate in inflamed tissues, parenteral iron should not be given to patients with severe inflammation or infection of the kidney or liver.

WARNINGS AND PRECAUTIONS

Parentally administered iron preparations can cause allergic or anaphylactoid reactions. In the case of a mild allergic reaction, antihistamines should be administered immediately. Facilities for cardiopulmonary resuscitation must be available. Caution is recommended in patients with allergies and hepatic and renal insufficiency. The incidence of undesirable side effects in patients with angiocardiopathy may increase the related cardiovascular complications.

Patients with bronchial asthma, with low iron binding capacity and/or folic acid deficiency are particularly at risk of an allergic or anaphylactoid reaction. Parenterally administered iron preparations can unfavourably influence the course of infections in children.

Some cases of anaphylactic reactions after parenteral administration of iron having been described, it is recommended to initiate the treatment with a test dose to test the sensitivity of the patient.

Use in pregnancy and lactation

FERRUM H should not be administered in the first trimester of pregnancy. FERRUM H should only be administered in the second and third trimester of pregnancy if the benefits of

treatment outweigh the potential risk to the foetus. No controlled studies are available on animals or on pregnant women.

ADVERSE EFFECTS

Adverse reactions to parenteral FERRUM H have only been reported infrequently. However, the following reactions are known to have occurred after parenteral iron therapy:

Intramuscular Injection

Local reactions may include pain at the site of injection, local inflammation with inguinal lymphadenopathy, and lower quadrant abdominal pain. Systemic reactions after this form of administration are rare but may include anaphylaxis. (Reference is made to the following paragraph describing delayed systemic reactions).

Delayed systemic reactions

Delayed systemic reactions may include dizziness, syncope, a sensation of stiffening of the arms, legs or face, chest and back pain, arthralgia, chills, fever, rash, urticaria, angioneurotic oedema and generalised lymphadenopathy.

INTERACTIONS

As with all parenteral iron preparations, FERRUM H ampoules should not be administered concomitantly with oral iron preparations as the absorption of oral iron is reduced. Oral iron therapy should not commence until at least one week after the last iron injection.

Concomitant administration of ACE inhibitors can increase the systemic effect of parenteral iron preparations.

OVERDOSAGE

Not available.

PHARMACEUTICAL PRECAUTIONS

The ampoules should be stored below 25°C. Do not freeze. Protect from light.

MEDICINE CLASSIFICATION

Prescription Medicine

PACKAGE QUANTITIES

Cartons of 5 x 2 mL ampoules, each ampoule containing 100 mg Fe as iron polymaltose.

FURTHER INFORMATION

FERRUM H contains a macromolecular spherocolloidal complex of iron(III) hydroxide and the carbohydrate ligand polymaltose. The complex has a molecular weight of about 462,000.

The aqueous colloidal solution is sterile, pyrogen-free and approximates the pH and tonicity of the tissues.

Excipients

Water - purified, sodium hydroxide (for pH adjustment).

NAME AND ADDRESS

Exclusive New Zealand distributor:

Pharmacy Retailing (NZ) Limited
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58 Richard Pearse Drive
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DATE OF PREPARATION

2nd February 2011