Ballarat Health Services

DRUG GUIDELINE

IRON POLYMALTOSE (Intravenous infusion)

SCOPE (Area): **FOR USE IN:** All wards
EXCLUSIONS: Paediatrics (seek Paediatrician advice)
SCOPE (Staff): Medical, Nursing and Pharmacy

Note: This guideline does not cover the use of iron infusions in dialysis - see Drugs used in the Dialysis Unit (CPP0542).
Iron sucrose (Venofer®) is reserved for use in dialysis patients under PBS scripts only.
For ferric carboxymaltose (Ferinject®) see DRG0049 - Ferric Carboxymaltose (intravenous infusion).

BRAND NAMES
Ferrosig®.
Ferrum H®.
Also known as iron polymaltose complex and iron polymaltose compound.

PHARMACOLOGY AND PHARMACOKINETICS
Iron is an essential element required for the formation of haemoglobin and myoglobin. Circulating iron polymaltose is ionised to Fe^{3+} and polymaltose. The majority of Fe^{3+} is bound to transferrin and transported to the bone marrow for incorporation into haemoglobin. The remainder is contained within the storage forms haemosiderin and ferritin or incorporated into myoglobin or haem containing enzymes. Only very small amounts of iron are excreted. The conservation of body iron and the lack of an excretory mechanism for excess iron may lead to iron overload if iron intake is excessive. Polymaltose is either metabolised or excreted.

INDICATIONS
- For the treatment of iron deficiency (as determined by iron studies no older than 4 months), when oral preparations are ineffective or cannot be used. All orders must be confirmed by a Registrar or Consultant.
  Iron deficiency is defined as:
  - Ferritin less than 30 microg/L (iron deficiency)
  - Ferritin 30 microg/L to 100 microg/L (possible iron deficiency in the presence of inflammation, chronic disease or high C-reactive protein)
  - Serum ferritin greater than 100 microg/L and Transferrin saturation less than 20% (functional iron deficiency)

CONTRAINDICATIONS
- Severe allergic reaction to iron polymaltose.
- Anaemia not caused by simple iron deficiency.
- Iron overload.
- Uncontrolled hyperparathyroidism.

- Patients with severe inflammation or infection of the kidney or liver (e.g. decompensated hepatic cirrhosis, infectious hepatitis) as iron tends to accumulate in inflamed tissues.

PRECAUTIONS

- **Previous adverse reaction (non-severe) to iron polymaltose** - seek Specialist advice as iron polymaltose may still be given. A premedication is usually indicated for these patients.
- **Patients with the following conditions may be at a higher risk of allergic reactions (including anaphylaxis)**
  - Bronchial asthma,
  - Low iron binding capacity
  - Folic acid deficiency
  - History of allergic disorders
  - Hepatic insufficiency
  - Cardiovascular disease
- **Transfusion-dependent anaemias** - risk of iron overload; avoid iron supplementation.
- **Rheumatoid arthritis or other inflammatory disorders** - may be at greater risk of delayed reactions including fever or exacerbation or reactivation of joint pain.

PREGNANCY AND BREASTFEEDING

Seek specialist advice before prescribing, information may update regularly.
Note: The Australian Drug Evaluation Committee lists iron polymaltose as Category A (Drugs which have been taken by a large number of pregnant women and women of childbearing age without any proven increase in the frequency of malformations or other direct or indirect harmful effects on the foetus having been observed), but iron polymaltose is contraindicated by the manufacturer in the first trimester of pregnancy - seek Specialist advice.

DRUG INTERACTIONS

- **Oral iron** - oral iron absorption is decreased and oral therapy should not commence until at least one week after last dose of parenteral iron.
- **Angiotensin converting enzyme inhibitors** - may increase the incidence of adverse effects associated with the iron infusion (e.g. abdominal cramps, nausea, vomiting and hypotension).

DOSAGE AND ADMINISTRATION

Information for prescribing and administering iron polymaltose infusion:

1.) Consider the possibility of anaphylactoid reactions

- **Whilst rare, these reactions typically occur within the first few minutes of administration and are generally characterised by sudden onset of respiratory difficulties, angioedema, urticaria, tachycardia and hypotension.**
  If these symptoms occur:
  - **STOP the infusion immediately**
  - **Contact the Medical Officer**
  - **Call a MET response or Code Blue**
  - **Ensure resuscitation trolley is available at the bedside**
- **Iron infusions are only to be administered during the hours medical staff access is readily available to that area. The time the infusion is to be given must be discussed between Medical and Nursing staff prior to the infusion being prepared.**
- **The infusion is started at a low rate as a 'test dose' to ascertain if the patient will have a major allergic reaction.**

- **The Medical Officer must remain with the patient for the first 5 minutes of the infusion.**
- **The patient must be directly observed and monitored by the nurse during the first 15 minutes of infusion.**

2.) General Information

- **Iron polymaltose must be diluted prior to use** - see below for more information.
- **Iron polymaltose is compatible only with sodium chloride 0.9%, and is not to be mixed with other drugs or solutions.**
- Premedications are usually only given if the patient has had a previous reaction to an iron infusion, or if the Prescriber determines the patient is at an increased risk of anaphylaxis. If required hydrocortisone 100mg IV AND an antihistamine (e.g. promethazine 25mg IM OR loratadine/cetirizine 10mg oral) are given 30 minutes prior to administration of iron.
- Promethazine may cause drowsiness the day of the infusion and the day after. Ensure patients receiving promethazine are made aware that if impaired they should not drive.
- Note: Although the Ferrum H® product information does not recommend IV administration, in practice the formulation and pH appears to be the same as Ferrosig® and these products are used interchangeably.
- Serum iron determinations may not be meaningful for three weeks following intravenous iron administration.

3.) Information for Prescribers

- Baseline haemoglobin and iron studies are required (no older than 4 months) – see Indications.
- Review patients risk of an allergic reaction - is premedication required?
- To prescribe on the Intravenous Orders chart MR/645 as elemental iron (dosage outlined below this box). Each ampoule contains **elemental iron** 100 mg/2 mL, in the form of iron polymaltose complex 318 mg/2 mL. Record the patient's allergies, weight, height (required for calculation of ideal body weight) and haemoglobin near the bradma on the MR/645. Once completed give chart to Nursing staff.
- **The Prescriber is to remain with the patient for the first 5 minutes of the infusion.**
- Iron infusions may affect some blood tests and Radiology tests - see Monitoring for more information.

4.) Information for Nursing staff

- Obtain patient weight and height to assist the Prescriber with dose calculation.
- Page ward Pharmacist or fax Intravenous Orders chart to Pharmacy to order stock. Include date and time infusion is to be given.
- **The patient must be directly observed and monitored by the nurse during the first 15 minutes of infusion.**
- **Suction, oxygen and resuscitation trolley needs to be available.**
- **Review what to do if an adverse reaction occurs as outlined above.**
- **The patient should be in an area where they can be closely monitored throughout the duration of the infusion.**
- Add the prescribed dose (see Dosage information below this box) of iron polymaltose via a 5 micron filter (to remove glass particles - available from Pharmacy or Supply) to the infusion bag. Protect infusion bag from light by using a black (or other light protective) bag (available from Pharmacy), once prepared and during administration.
- **Record vital signs, including heart rate, blood pressure, respiratory rate, temperature and oxygen saturation:**
  - Prior to commencement of infusion (baseline)
  - Every 5 minutes for the first 15 minutes (with first observations after the infusion commences before the Prescriber leaves)
  - Every 30 minutes for the remainder of the infusion.

- **The patient should remain under supervision for at least one hour after the infusion is completed.**
- Infusion-related side effects include nausea, headache, arthralgia, chest pain, fever, cough, faintness, rash and injection site reactions. If any of these occur then the infusion should be stopped and the reactions discussed with Prescriber. Depending on the reaction the infusion may be restarted at a lower rate or ceased. Consider promethazine 12.5-25mg IM if a mild allergic reaction e.g. rash.
- **See below for information regarding preparing infusion and rates.**

IV infusion:

Use iron (elemental) 100 mg/2 mL ampoules (equivalent to iron polymaltose complex 318 mg/2 mL) to make up infusion.
Elemental Iron (see Dose Calculation below) added to a 500 mL sodium chloride 0.9% IV bag.
Maximum concentration: 5 mg/mL.
Maximum dose: 2500 mg/500 mL (addition of 50 mL iron from TWENTY FIVE 100 mg/2 mL ampoules).
Starting rate (test dose): 40 mL/hr for the first 50 mL (one hour and 15 minutes). This is a test dose given at a slow rate to ascertain if the patient will have a major allergic reaction - see box above.
Rate increase: If the test dose is well tolerated and no signs of adverse reaction after the first 1 hr and 15 minutes, increase the infusion rate to 120 mL/hr for the remainder of the infusion. Total infusion time is approximately 5 hours.
Maximum rate: 120 mL/hr after test dose tolerated.
Stop infusion immediately if any adverse reaction is noted.
Note: Nursing staff may first remove the same number of mL from the IV bag (as they are adding of iron polymaltose) before adding the iron polymaltose if they are concerned the volume won't fit.

Fluid restricted patients may have their dose in 250 mL, but only to a maximum dose of 1250 mg (maximum concentration = 5 mg/mL). **The rate of administration is to be halved, and total infusion time is unchanged.**

IV infusion (Fluid Restricted):

Use iron (elemental) 100 mg/2 mL ampoules (equivalent to iron polymaltose complex 318 mg/2 mL) to make up infusion.
Elemental Iron (see Dose Calculation below) added to a 250 mL sodium chloride 0.9%.
Maximum concentration: 5 mg/mL.
Maximum dose: 1250 mg/250 mL (addition of 25 mL iron from THIRTEEN 100 mg/2 mL ampoules).
Starting rate (test dose): 20 mL/hr for the first 25 mL (one hour and 15 minutes). This is a test dose given at a slow rate to ascertain if the patient will have a major allergic reaction - see box above.
Rate increase: If the test dose is well tolerated and no signs of adverse reaction after the first 1 hr and 15 minutes, increase the infusion rate to 60 mL/hr for the remainder of the infusion. Total infusion time is approximately 5 hours.
Maximum rate: 60 mL/hr after test dose tolerated.
Stop infusion immediately if any adverse reaction is noted.

Dose calculation:

Use the table below (from the manufacturer) to calculate the dose required using:

- **Ideal body weight** is used for calculating the iron dose (including for pregnant patients), except if actual body weight is less than ideal body weight in which case actual body weight is used. A table for determining ideal body weight is available from the Therapeutic Guidelines website http://online.tg.org.au/ip/ or Appendix 1.
- Hb levels - if the patient has received blood use the pre-blood Hb levels EXCEPT if massive transfusion (greater than 5 units of blood). In this case take into account that the transfusion of 1 unit of blood releases approximately 200 mg of elemental iron following the breakdown of the transfused red blood cells.

Iron Infusion Dosage Table

Each ampoule contains 100 mg/2 mL elemental iron.

Doses are to be prescribed as 'elemental iron (as iron polymaltose)'.

Wt*	Hb 6 g/dL			Hb 7.5 g/dL			Hb 9 g/dL			Hb 10.5 g/dL		
(kg)	mL	amps	mg	mL	amps	mg	mL	amps	mg	mL	amps	mg
40	27	13.5	1350	24	12	1200	22	11	1100	19	9.5	950
45	30	15	1500	26	13	1300	23	11.5	1150	20	10	1000
50	32	16	1600	28	14	1400	24	12	1200	21	10.5	1050
55	34	17	1700	30	15	1500	26	13	1300	22	11	1100
60	36	18	1800	32	16	1600	27	13.5	1350	23	11.5	1150
65	38	19	1900	33	16.5	1650	29	14.5	1450	24	12	1200
70	40	20	2000	35	17.5	1750	30	15	1500	25	12.5	1250
75	42	21	2100	37	18.5	1850	32	16	1600	26	13	1300
80	45	22.5	2250	39	19.5	1950	33	16.5	1650	27	13.5	1350
85	47	23.5	2350	41	20.5	2050	34	17	1700	28	14	1400
90	49	24.5	2450	43	21.5	2150	36	18	1800	29	14.5	1450

Maximum dose is 2500 mg = 50 mL from TWENTY FIVE ampoules

*** Weight is ideal body weight (unless actual body weight is less than ideal body weight) - see Appendix 1**

Alternatively, the following formula can be used to calculate the dose:

Use ideal body weight except if actual body weight is less than ideal body weight, in which case actual body weight is used. **- see Appendix 1 - Ideal Body Weight.**

Iron dose (mg) = [target Hb (g/dL)* - actual Hb (g/dL)] x weight (kg) x 2.4 + iron depot**

* Target Hb - Wt 34 kg or less = 13 g/dL, Wt greater than 34 kg = 15 g/dL

** Iron depot - Wt 34 kg or less = 15 mg/kg, Wt 34 kg or greater = 500 mg

(NB. For conversion of Hb units of measure: 1.0 g/dL = 10 g/L)

Example of calculation:

For a patient with an ideal body weight of 60 kg and Hb = 8 g/dL, and the target Hb is set to be 15 g/dL and the iron depot = 500 mg

The required iron dose = (15 - 8) x 60 x 2.4 + 500 mg = 1508 mg

(This approximates to 1500 mg = 15 ampoules = 30 mL)

General Administration Information

- **Infusion pump:** Alaris® LVP with Guardrails.
- **Routes of administration:**
  IV injection: No
  IV intermittent infusion: Not usually
  IV continuous infusion: Yes
  IM injection: Not usually, causes pain and may discolour skin. See 'Yellow book' for details
  Subcut injection: No
- **Compatible/incompatible IV drugs/fluids:**
  Iron Polymaltose is compatible only with sodium chloride 0.9%, and is not to be mixed with other drugs or solutions.
  Consult the Australian Injectable Drugs Handbook ('Yellow book') in your ward area. **Assume all unlisted drugs and IV fluids are incompatible – contact Pharmacy for further advice.**

MONITORING (INCLUDING BLOOD TESTS)

- Baseline haemoglobin and iron studies (no older than 4 months).
- Effect on blood tests - contact Pathology for further information
  - blood samples obtained up to 4 hours after the iron infusion may have a brown colour
  - serum calcium may be falsely decreased and serum bilirubin falsely elevated
  - iron measurements may not be meaningful for 3 weeks
- Effect on Radiology tests - contact Radiology for further information
  - may effect tests using technetium Tc-99m diphosphonate and Ga-67 gallium citrate

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NURSING PRACTICE POINTS

- See 'Information for prescribing and administering iron polymaltose infusion' under Dosage and Administration.

ADVERSE EFFECTS

- **Anaphylaxis** - occurs rarely, see 'Information for prescribing and administering iron polymaltose infusion' under Dosage and Administration for more information.
- **Infrequently** - flushing, sweating, taste disturbance, nausea, vomiting, headache, dizziness, syncope, chest and back pain, hypophosphataemia, arthralgia, myalgia, tachycardia, changes in BP, chest pain, chills and fever, generalised lymphadenopathy, bronchospasm with dyspnoea, rash, urticaria, hypersensitivity (e.g. angioedema, anaphylaxis) and sensation of stiffening of the arms, legs and face.

Some adverse effects may occur up to 2 days after the infusion and last for up to 8 days.

DRUG PRESENTATIONS, LOCATION AND STORAGE

Iron (elemental) 100 mg/2 mL ampoules (equivalent to iron polymaltose complex 318 mg/2 mL).
Imprest locations (at the time of guideline development): Ampoules for infusion must be obtained from the Pharmacy.
Store below 25°C. Protect from light. Do not freeze.

APPENDIX 1 - Ideal Body Weight

Height		Ideal body weight (kg)*	
cm	**Feet and inches**	**female**	**male**
155	5‘1”	48	53
160	5’3”	53	57
165	5’5”	57	62
170	5’7”	62	66
175	5’9”	66	71
180	5’11”	71	75
185	6’1”	75	80
190	6’3”	80	84
195	6’5”	84	89
200	6’7”	89	93
205	6’9”	93	98
210	6’11”	98	102

* Ideal weight for male = 50 kg + 0.9 kg/each cm over 152 cm (2.3 kg/each inch over 5 feet)
Ideal weight for female = 45.5 kg + 0.9 kg/each cm over 152 cm (2.3 kg/each inch over 5 feet)