REGIONAL ADULT PARENTERAL DRUG MONOGRAPH

GENERIC NAME

Ferric Derisomaltose

Effective Date: Sept 16 2020 **Revised Date:** Nov 2024	CLASSIFICATION **Iron replacement**	OTHER NAMES **Monoferric** **iron isomaltoside**	PAGE 1 of 2

ADMINISTRATION POLICY:

IV Bolus - May be administered by nurse
IV Intermittent (preferred) - May be administered by a nurse
IM - Not recommended
Subcut - Not recommended

RECONSTITUTION/DILUTION/ADMINISTRATION:

Available as: Elemental iron 100 mg/mL vial

IV Intermittent: (preferred) 500 mg dose: Administer at 170 mL/hour for 10 minutes. If tolerated increase to 340 mL/hour for remainder of infusion (total infusion time approximately 25 mins)

1000 mg dose: Administer at 120 mL/hour for 10 minutes. If tolerated increase to 240 mL/hour for remainder of infusion (total infusion time approximately 35 mins)

Dose	Dose Preferred Diluent Volumes Bag size NaCl 0.9%
500 mg	100 mL
1000 mg	100 mL

IV Bolus: For doses 500 mg or less
Undiluted or diluted in a maximum of 20 mL normal saline over 2 minutes

Maximum rate: IV Bolus: 250 mg/minute
IV Intermittent: Doses 1000 mg or less over at least 20 minutes
Doses over 1000 mg over at least 30 minutes

Maximum concentration: 100 mg/mL
Minimum concentration: 1 mg/mL

DOSAGE:

Dosage is individualized based on patient's iron deficit.
Iron deficit can be calculated with using the Ganzoni formula or the simplified table as below.

Hemoglobin (g/L)	**Weight**		
	Less than 50 kg	**50 to less than 70 kg**	**Greater than or equal to 70 kg**
Greater than or equal to 100	500 mg	1000 mg	*Dose 1: 1000 mg Dose 2: 500 mg Total cumulative dose: 1500 mg
Less than 100	*Dose 1: 500 mg Dose 2: 500 mg Total cumulative dose: 1000 mg	*Dose 1: 1000 mg Dose 2: 500 mg Total cumulative dose: 1500 mg	*Dose 1: 1000 mg Dose 2: 1000 mg Total cumulative dose: 2000 mg

*Dose 1 and 2 given at least 7 days apart

Maximum single dose: IV bolus: 500 mg (once a week)

REGIONAL ADULT PARENTERAL DRUG MONOGRAPH

GENERIC NAME

Ferric Derisomaltose

IV Intermittent: 1500 mg (once a week)

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STABILITY/COMPATIBILITY:

Stability of Final Admixture: 8 hours at room temperature
Compatibility: Compatible with normal saline only

PRECAUTIONS, POTENTIAL ADVERSE REACTIONS:

- Cardiovascular: hypertension, hypotension, peripheral edema, chest pain
- Neurologic: headache, dizziness, fatigue, paresthesia
- Dermatologic: rash
- Endocrine: hypophosphatemia
- Gastrointestinal: nausea, constipation, diarrhea, vomiting, abdominal pain
- Immunologic: anaphylaxis
- Neuromuscular: arthralgia, back pain, myalgia, limb pain, muscle spasm
- Respiratory: cough, dyspnea
- Other: fever, influenza-like symptoms

ADDITIONAL NOTES AND NURSING CONSIDERATIONS:

- Observe patients for signs and symptoms of hypersensitivity including anaphylaxis during and for at least 30 minutes following each infusion. If hypersensitivity reaction occurs, stop infusion and notify prescriber. Consider restarting infusion at reduced rate if symptoms abate.
- Serious hypersensitivity reactions, including anaphylactic-type reactions (some life threatening and fatal) have been reported. Patients with history of asthma, eczema or other atopic allergy and inflammatory conditions (eg. systemic lupus erythematosus, rheumatoid arthritis) are at a higher risk of developing hypersensitivity reactions.
- Monitor vital signs prior to the infusion and then every 30 minutes afterward. Observe patient for at least 30 minutes after infusion has completed
- Significant hypotension has been reported. Hypotension may be related to rate of administration; avoid rapid IV injection. Monitor during and for greater than or equal to 30 minutes after each administration
- Test doses are not required
- Avoid use in patients with hepatic dysfunction (ALT and /or AST elevations greater than 3 x ULN). Use is contraindicated in patients with decompensated liver cirrhosis or active hepatitis.
- Fetal bradycardia has been observed following maternal administration.
- Traces may be found in breast milk, monitor breast fed infant for constipation and diarrhea
- The Ganzoni formula is the preferred method of calculating iron deficit
- Transient, asymptomatic hypophosphatemia has been reported
- Patients receiving regular parenteral iron require monitoring of hematologic parameters and iron indices. Oral iron salts may reduce its absorption and should begin 5 days after the last dose of IV iron isomaltoside
- If the cumulative iron dose exceeds 20 mg/kg body weight, the dose must be split in two administrations with an interval of at least one week. It is recommended whenever possible to give 20 mg iron/kg body weight in the first administration.