

One Year Post Exclusivity Adverse Event Review: Sodium ferric gluconate complex

**Pediatric Advisory Committee Meeting
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Background Drug Information

- **Drug:** Ferrlecit[®] (sodium ferric gluconate complex in sucrose injection)
- **Therapeutic Category:** Hematinic
- **Sponsor:** Watson Pharma Inc.
- **Indication:** Treatment of iron deficiency anemia in adult and pediatric patients ≥ 6 years undergoing chronic hemodialysis who are receiving supplemental epoetin therapy
- **Original Market Approval:** February 18, 1999
- **Pediatric Exclusivity Granted:** March 24, 2004

Sodium ferric gluconate complex

- Labeling changes
 - Safety and effectiveness established in pediatric patients 6-15 years old; patients <6 years of age not studied
 - Information on dose, PK parameters and AE profile included
- Inpatient use: 11,521-13,899 discharges during 2003-2004 for all ages; < 1% in pediatric patients¹; no outpatient data available to FDA

Summary:

Sodium ferric gluconate complex

- Since exclusivity, one labeled pediatric adverse event
- This completes the one-year post-exclusivity AE reporting as mandated by BPCA.
- FDA recommends routine monitoring of AEs for sodium ferric gluconate complex in all populations.
- Does the Advisory Committee concur?

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