Viatris Announces Approval of First Generic Iron Sucrose Injection in the U.S.

August 11, 2025

Approval is Another Milestone of Viatris' Ability to Successfully Develop Complex Generic Medicines

Approval Granted with Competitive Generic Therapy Eligibility for 100mg/5mL and 200mg/10mL Strengths; Provides Eligibility for 180 Days of Exclusivity

PITTSBURGH, Aug. 11, 2025 /PRNewswire/ -- Viatris Inc. (Nasdaq: VTRS), a global healthcare company, today announced the U.S. Food and Drug Administration (FDA) has approved Iron Sucrose Injection, USP, an intravenous iron replacement product used to treat iron deficiency anemia (IDA) in adult and pediatric patients (2 years of age and older) with chronic kidney disease (CKD). IDA is a common complication of CKD and is associated with a significantly heightened risk of cardiovascular morbidity and higher mortality rates. Iron Sucrose Injection, USP, the first generic version of Venofer® Injection, is expected to be available imminently in single dose vials in the following strengths: 50 mg/2.5mL, 100mg/5mL and 200mg/10mL.

Viatris Chief R&D Officer Philippe Martin said, "The first FDA approval of a generic iron sucrose is an important advancement for patients with CKD and iron deficiency anemia and a testament to Viatris' advanced technical and manufacturing capabilities. This complex product was developed in-house, and after a number of years working closely with the FDA we are pleased to accomplish this important milestone."

Viatris' robust complex injectable pipeline includes multiple difficult-to-develop and manufacture assets across several therapeutic areas and patient types. The pipeline also includes ferric carboxymaltose injection – another iron replacement product.

Viatris Chief Commercial Officer Corinne Le Goff said, "The U.S. launch of this first-to-market generic iron sucrose will be an important addition to the treatment landscape for chronic kidney disease patients with iron deficiency, and will help increase sustainable access to this critical therapy. Iron sucrose builds on Viatris' large and diversified global business and will further strengthen our generics portfolio."

The FDA granted Viatris a competitive generic therapy (CGT) designation for iron sucrose 100 mg/5 mL and 200 mg/10 mL strengths. CGT designation allows for expedited review of generic versions of medications with "inadequate generic competition." This regulatory pathway helps to expedite market entry of generic drugs and provides eligibility for 180 days of exclusivity upon commercial marketing of the medicine.

Venofer® had annual sales of approximately $515M in the U.S. as of June 30, 2025, according to IQVIA.

Iron Sucrose Injection, For Intravenous Use

INDICATION AND USAGE

Iron sucrose injection is indicated for the treatment of iron deficiency anemia (IDA) in patients with chronic kidney disease (CKD).

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS
Known hypersensitivity to iron sucrose.

WARNINGS AND PRECAUTIONS

Hypersensitivity reactions: Serious hypersensitivity reactions, including anaphylactic-type reactions, some of which have been life-threatening and fatal, have been reported in patients receiving iron sucrose. Patients may present with shock, clinically significant hypotension, loss of consciousness, and/or collapse. If hypersensitivity reactions or signs of intolerance occur during administration, stop iron sucrose immediately. Monitor patients for signs and symptoms of hypersensitivity during and after iron sucrose administration for at least 30 minutes and until clinically stable following completion of the infusion. Only administer iron sucrose when personnel and therapies are immediately available for the treatment of serious hypersensitivity reactions. Most reactions associated with intravenous iron preparations occur within 30 minutes of the completion of the infusion.

Hypotension: Iron sucrose may cause clinically significant hypotension. Monitor for signs and symptoms of hypotension following each administration of iron sucrose. Hypotension following administration of iron sucrose may be related to rate of administration and/or total dose delivered.

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 iron sucrose require periodic monitoring of hematologic and iron parameters (hemoglobin, hematocrit, serum ferritin, and transferrin saturation). Do not administer iron sucrose to patients with evidence of iron overload. 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.

ADVERSE REACTIONS

Adult Patients: The most common adverse reactions (≥2%) include diarrhea, nausea, vomiting, headache, dizziness, hypotension, pruritus, pain in extremity, arthralgia, back pain, muscle cramp, injection site reactions, chest pain, and peripheral edema.

Pediatric Patients: The most common adverse reactions (≥2%) are headache, respiratory tract viral infection, peritonitis, vomiting, pyrexia, dizziness, cough, nausea, arteriovenous fistula thrombosis, hypotension, and hypertension.

Post-Marketing Experience

Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure. In post-marketing safety studies of iron sucrose in 1,051 patients with HDD-CKD, adverse reactions reported by >1% were cardiac failure congestive, sepsis, and dysgeusia.

- *Immune system disorders:* anaphylactic-type reactions, angioedema
- *Psychiatric disorders:* confusion
- *Nervous system disorders:* convulsions, collapse, light-headedness, loss-of-consciousness
- *Cardiovascular system:* bradycardia, shock, acute myocardial ischemia with or without myocardial infarction or with in-stent thrombosis in the context of a hypersensitivity reaction
- *Respiratory, thoracic, and mediastinal disorders:* bronchospasm, dyspnea
- *Musculoskeletal and connective tissue disorders:* back pain, swelling of the joints
- *Renal and urinary disorders:* chromaturia
- *General disorders and administration site conditions:* hyperhidrosis

Symptoms associated with iron sucrose total dosage or infusing too rapidly included hypotension, dyspnea, headache, vomiting, nausea, dizziness, joint aches, paresthesia, abdominal and muscle pain, edema, and cardiovascular collapse. These adverse reactions have occurred up to 30 minutes after the administration of iron sucrose injection. Reactions have occurred following the first dose or subsequent doses of iron sucrose. Slowing the infusion rate may alleviate symptoms.

Injection site discoloration has been reported following extravasation. Assure stable intravenous access to avoid extravasation.

DRUG INTERACTIONS

Iron sucrose may reduce the absorption of concomitantly administered oral iron preparations.

USE IN SPECIFIC POPULATIONS

Pregnancy: Risk Summary-Clinical Considerations

Untreated IDA in pregnancy is associated with adverse maternal outcomes such as post-partum anemia. Adverse pregnancy outcomes associated with IDA include increased risk for preterm delivery and low birth weight.

Severe adverse reactions including circulatory failure (severe hypotension, shock including in the context of anaphylactic reaction) may occur in pregnant women with parenteral iron products (such as iron sucrose) which may cause fetal bradycardia, especially during the second and third trimester.

Geriatric Use

Dose administration to an elderly patient should be cautious, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

For additional Safety Information, please see Full Prescribing Information.

About Viatris
Viatris Inc. (NASDAQ: VTRS) is a global healthcare company uniquely positioned to bridge the traditional divide between generics and brands, combining the best of both to more holistically address healthcare needs globally. With a mission to empower people worldwide to live healthier at every stage of life, we provide access at scale, currently supplying high-quality medicines to approximately 1 billion patients around the world annually and touching all of life's moments, from birth to the end of life, acute conditions to chronic diseases. With our exceptionally extensive and diverse portfolio of medicines, a one-of-a-kind global supply chain designed to reach more people when and where they need them, and the scientific expertise to address some of the world's most enduring health challenges, access takes on deep meaning at Viatris. We are headquartered in the U.S., with global centers in Pittsburgh, Shanghai and Hyderabad, India. Learn more at **viatris.com** and **investor.viatris.com,** and connect with us on **LinkedIn, Instagram, YouTube** and **X.**

Forward-Looking Statements

This press release includes statements that constitute "forward-looking statements." These statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements may include statements that approval is another milestone of Viatris' ability to successfully develop complex generic medicines; approval granted with competitive generic therapy eligibility for 100mg/5mL and 200mg/10mL strengths; provides 180 days of exclusivity; Iron Sucrose Injection, USP, the first generic version of Venofer® Injection,

is expected to be available imminently available in single dose vials in the following strengths: 50 mg/2.5mL, 100mg/5mL and 200mg/10mL; the first FDA approval of a generic iron sucrose is an important advancement for patients with CKD and iron deficiency anemia and a testament to Viatris' advanced technical and manufacturing capabilities; the U.S. launch of this first-to-market generic iron sucrose will be an important addition to the treatment landscape for chronic kidney disease patients with iron deficiency, and will help increase sustainable access to this critical therapy; iron sucrose builds on Viatris' large and diversified global business and will further strengthen our generics portfolio. Because forward-looking statements inherently involve risks and uncertainties, actual future results may differ materially from those expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to: whether any other companies have simultaneously launched a generic iron sucrose injection in the U.S. and have shared exclusivity for the first 180 days; actions and decisions of healthcare and pharmaceutical regulators; our ability to comply with applicable laws and regulations; changes in healthcare and pharmaceutical laws and regulations in the U.S. and abroad; any regulatory, legal or other impediments to Viatris' ability to bring new products to market; products in development and/or that receive regulatory approval may not achieve expected levels of market acceptance, efficacy or safety; longer review, response and approval times as a result of evolving regulatory priorities and reductions in personnel at health agencies; Viatris' or its partners' ability to develop, manufacture, and commercialize products; the scope, timing and outcome of any ongoing legal proceedings, and the impact of any such proceedings on Viatris; Viatris' failure to achieve expected or targeted future financial and operating performance and results; goodwill or impairment charges or other losses; any changes in or difficulties with the Company's manufacturing facilities; risks associated with international operations; changes in third-party relationships; the effect of any changes in Viatris' or its partners' customer and supplier relationships and customer purchasing patterns; the impacts of competition; changes in the economic and financial conditions of Viatris or its partners; uncertainties regarding future demand, pricing and reimbursement for the Company's products; uncertainties and matters beyond the control of management, including but not limited to general political and economic conditions, potential adverse impacts from future tariffs and trade restrictions, inflation rates and global exchange rates; and the other risks described in Viatris' filings with the Securities and Exchange Commission ("SEC"). Viatris routinely uses its website as a means of disclosing material information to the public in a broad, non-exclusionary manner for purposes of the SEC's Regulation Fair Disclosure (Reg FD). Viatris undertakes no obligation to update these statements for revisions or changes after the date of this press release other than as required by law.

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