

Supplemental Approvals

Generic Name (Trade Name—Company)

May 15, 2018

Epoetin alfa-epbx

(Retacrit—Hospira)

FDA approves first epoetin alfa biosimilar for treatment of anemia

Uses/Notes

FDA approved [epoetin alfa-epbx](#) as a biosimilar to epoetin alfa (Epogen/Procrit) to treat anemia caused by chronic kidney disease, chemotherapy, or use of zidovudine in patients with HIV infection.

Epoetin alfa-epbx is also approved for use before and after surgery to reduce the chance that red blood cell transfusions will be needed because of blood loss during surgery.

Approval was based on a review of evidence that included extensive structural and functional characterization, animal study data, human pharmacokinetic and pharmacodynamic data, clinical immunogenicity data, and other clinical safety and effectiveness data that demonstrate the product is biosimilar to epoetin alfa. It has been approved as a [biosimilar](#), not as an [interchangeable product](#).

The most common adverse effects in clinical studies of the reference product were high blood pressure, joint pain, muscle spasm, fever, dizziness, medical device malfunction, blood vessel blockage, respiratory infection, cough, rash, injection site irritation, nausea, vomiting, muscle pain, inflammation of the mouth and lips, weight decrease, reduction in white blood cells, bone pain, high blood sugar, insomnia, headache, depression, difficulty swallowing, low blood potassium, blood clots, itching, headache, injection site pain, and chills.

Like epoetin alfa, the biosimilar must be dispensed with a patient Medication Guide and contains a boxed warning to alert health professionals and patients about increased risks of death, heart problems, stroke, and tumor growth or recurrence.

Additional warnings include high blood pressure; seizures; a condition in which the bone marrow stops making red blood cells, thus causing anemia; serious allergic reactions; and severe skin reactions.

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