

FDA Public Health Advisory
Epoetin alfa (marketed as Procrit, Epogen)
Darbepoetin alfa (marketed as Aranesp)

For updated information, please see the Public Health Advisory issued on March 9, 2007 at <http://www.fda.gov/cder/drug/advisory/RHE2007.htm>

Today, *The New England Journal of Medicine* published the results of a research study about Procrit, an erythropoiesis-stimulating agent (ESA) also known as recombinant human erythropoietin. The study found a higher chance of the combination of death, heart attack, hospitalizations for heart failure and stroke in patients with chronic kidney disease who are not on dialysis and were treated with Procrit to raise their hemoglobin levels higher than what the labeling for the product recommends. Procrit, like the other ESAs Epogen, and Aranesp, increases blood hemoglobin levels, the oxygen carrying component of blood, by increasing the number of red blood cells in the body. These products are used to treat anemia in certain patients.

The maximum treatment level recommended in product labeling for all approved ESAs is to raise blood hemoglobin levels to no higher than 12 g/dL. The results of this latest study emphasize the importance of following this recommendation.

In light of this research study, FDA is advising the following:

- To reduce serious complications from the use of ESAs, healthcare professionals should be familiar with the recommendations in the product labeling to maintain hemoglobin levels between 10 to 12 g/dL.
- Frequent tests to monitor blood hemoglobin levels are an important component of an ongoing ESA treatment plan. Healthcare professionals should talk with their patients about the importance of keeping appointments for simple blood tests to monitor hemoglobin levels.
- Patients should contact their doctor if they feel any worsening in shortness of breath, pain or the swelling in the legs or increases in blood pressure.

The New England Journal of Medicine article, published on November 16, 2006, presented the results of the Correction of Hemoglobin and Outcomes in Renal Insufficiency (CHOIR) study. The CHOIR study evaluated the potential benefit and harm from treatment with Procrit in patients with chronic kidney disease who are not on dialysis. In the study, harm was defined as a group of effects that included death, heart attack, hospitalizations for heart failure and stroke. The research found that patients in the study who were treated with Procrit to raise their blood hemoglobin concentration to the higher 13.5 g/dL level experienced more death and life-threatening harm than those who were treated to raise their blood hemoglobin concentration to the lower 11.3 g/dL level.

The FDA is working to fully evaluate the CHOIR study data and to determine if any additional actions are necessary in order to optimize the use of erythropoiesis-stimulating agents. FDA plans to notify healthcare providers and patients as additional information becomes available.

The FDA urges both healthcare providers and patients to report adverse events to MedWatch. MedWatch reports may be made by phone: 1-800-FDA-1088; fax: 1-800-FDA-0178; or via the Internet at <http://www.fda.gov/medwatch/index.html>