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FDA Public Health Advisory Erythropoiesis-Stimulating Agents (ESAs)

Epoetin alfa (marketed as Procrit, Epogen), Darbepoetin alfa (marketed as Aranesp)

The issues described in this Alert have been addressed in product labeling.

Recent reports of studies with erythropoiesis-stimulating agents (ESAs) have shown a higher chance of serious and life-threatening side effects and greater number of deaths in patients treated with these agents. ESAs stimulate the bone marrow to make more red blood cells and are FDA approved for use in reducing the need for blood transfusions in patients with chronic kidney failure, patients with cancer on chemotherapy, patients scheduled for major surgery (except heart surgery) and patients with HIV that are using AZT. Because all ESAs work the same way, the findings from these studies apply to all ESAs; the FDA is re-evaluating the safe use of this drug class.

Patients currently using or considering the use of an ESA should know the following:

- A higher chance of death and an increased rate of tumor growth were reported in patients with advanced head and neck cancer receiving radiation therapy and in patients with metastatic breast cancer receiving chemotherapy, when ESAs were given to maintain hemoglobin levels of more than 12 g/dL.
- A higher chance of death was reported and no fewer blood transfusions were received when ESAs were given to patients with cancer and anemia not receiving chemotherapy.
- A higher chance of death was reported and an increased number of blood clots, strokes, heart failure, and heart attacks was reported in patients with chronic kidney failure when ESAs were given to maintain hemoglobin levels of more than 12 g/dL.
- A higher chance of blood clots was reported in patients who were scheduled for major surgery and given ESAs.
- ESAs are not approved for treatment of the symptoms of anemia, such as fatigue in patients with cancer, surgical patients and patients with HIV.
- If you have any questions you should talk with your health care provider.

Important study results include the following:

- Patients with chronic kidney failure had an increased number of deaths and of non-fatal heart attacks, strokes, heart failure, and blood clots when ESAs were adjusted to maintain higher red blood cell levels (hemoglobin more than 12 g/dL).
- Patients with head and neck cancer receiving radiation therapy had faster tumor growth when ESAs were adjusted to maintain hemoglobin levels higher than 12 g/dL.
- Patients with cancer not receiving chemotherapy died sooner and had no fewer blood transfusions when ESAs were given according to the dosing recommendations for cancer patients receiving chemotherapy.
- Patients scheduled for orthopedic surgery who received ESAs to reduce blood transfusions during and after surgery had more blood clots than those not given an ESA.

Physicians who prescribe ESAs should consider the important study results above and:

- Understand that ESAs are given to decrease the need for red blood cell transfusions;
- Consider both the risks of transfusions and those of ESAs when deciding to prescribe an ESA;
- Adjust the dose of ESA to maintain the lowest hemoglobin level necessary to avoid the need for transfusions.
- Monitor patients' hemoglobin levels to ensure they do not exceed 12 g/dL;
- Understand that ESAs have not been shown to improve the outcomes of chemotherapy treatment (e.g., better tumor shrinkage, delay in tumor growth or longer time for survival); and
- Understand that in patients with cancer whose anemia is caused by chemotherapy and in patients with HIV whose anemia is caused by AZT (zidovudine), there are no data to support claims of improvement in health-related quality of life, including effects on fatigue, energy or strength.

FDA and Amgen, the manufacturer of these products, and Ortho Biotech Products, L.P, a Johnson & Johnson Pharmaceuticals Research and Development subsidiary, the distributor of Procrit, have agreed to change the labeling for Aranesp, Epogen, and Procrit to reflect the new safety information and to provide additional instructions for their use.

FDA-approved uses of ESAs are: for the treatment of anemia in chronic kidney failure patients, in patients with cancer whose anemia is caused by chemotherapy, in patients with HIV whose anemia is caused by AZT (zidovudine), and to reduce the number of transfusions in patients scheduled for major surgery (except heart surgery).

You can find more details about the use of ESAs in FDA's [Information for Healthcare Professional](#).

The FDA asks health care professionals and patients to report serious side effects after using ESAs to the FDA through the MedWatch program by phone (1-800-FDA-1088) or by the Internet at <http://www.fda.gov/medwatch>

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[↑ Back to Top](#) [↙ Recombinant Human Erythropoietins](#)

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